(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 December 2003 (18.12.2003)

PCT

(10) International Publication Number
WO 03/103476 A2

(51) International Patent Classification[7]: A61B

(21) International Application Number: PCT/US03/17715

(22) International Filing Date: 5 June 2003 (05.06.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/386,327 5 June 2002 (05.06.2002) US

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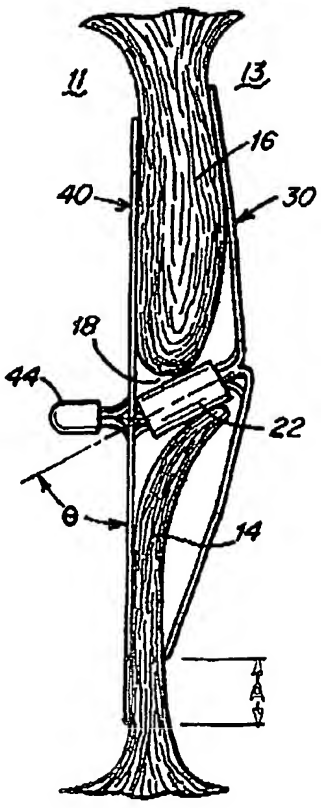
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

[Continued on next page]

(54) Title: PATENT FORAMEN OVALE (PFO) CLOSURE DEVICE WITH RADIAL AND CIRCUMFERENTIAL SUPPORT



(57) Abstract: The present invention provides a device for occluding an anatomical aperture, such as a septal defect or patent foramen ovale (PFO). The occluder includes two sides connected by an intermediate joint. Each of the sides includes at least one elongate element, which is arranged to form non-overlapping loops. Each loop has at least one radially-extending segment that is adjacent to a radially-extending segment of another loop. In at least some embodiments, at least one pair of adjacent radially-extending segments is connected. The loops of the device may be of various shapes, sizes, and configurations, and, in at least some embodiments, the loops have rounded peripheries. In some embodiments, at least one of the sides includes a tissue scaffold. When the occluder is deployed in vivo, the two sides are disposed on opposite sides of the septal tissue surrounding the aperture, thereby exerting a compressive force on the septal tissue that is distributed along both the outer periphery of the occluder and the radiallyextending segments.

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PATENT FORAMEN OVALE (PFO) CLOSURE DEVICE WITH RADIAL AND CIRCUMFERENTIAL SUPPORT

Field of the Invention

[0001] The present invention relates generally to an occlusion device for the closure of physical anomalies like septal apertures, such as patent foramen ovale and other septal and vascular defects.

Background of the Invention

[0002] A patent foramen ovale (PFO), illustrated in Figure 1, is a persistent, one-way, usually flap-like opening in the wall between the right atrium **11** and left atrium **13** of the heart **10**. Because left atrial (LA) pressure is normally higher than right atrial (RA) pressure, the flap usually stays closed. Under certain conditions, however, right atrial pressure can exceed left atrial pressure, creating the possibility that blood could pass from the right atrium **11** to the left atrium **13** and blood clots could enter the systemic circulation. It is desirable that this circumstance be eliminated.

[0003] The foramen ovale serves a desired purpose when a fetus is gestating in utero. Because blood is oxygenated through the umbilical chord, and not through the developing lungs, the circulatory system of a heart in a fetus allows the blood to flow through the foramen ovale as a physiologic conduit for right-to-left shunting. After birth, with the establishment of pulmonary circulation, the increased left atrial blood flow and pressure results in functional closure of the foramen ovale. This functional closure is subsequently followed by anatomical closure of the two over-lapping layers of tissue: septum primum **14** and septum secundum **16**. However, a PFO has been shown to persist in a number of adults.

[0004] The presence of a PFO is generally considered to have no therapeutic consequence in otherwise healthy adults. Paradoxical embolism via a PFO is considered in the diagnosis for patients who have suffered a stroke or transient ischemic attack (TIA) in the presence of a PFO and without another cause of ischemic stroke. While there is currently no definitive proof for a cause-effect relationship, many studies have confirmed a strong association between the presence of a PFO and the risk for paradoxical embolism or stroke. In addition, there is significant evidence that patients with PFO who have had a cerebral vascular event are at increased risk for future, recurrent cerebrovascular events.

[0005] Accordingly, patients with an increased future risk are considered for prophylactic medical therapy to reduce the risk of a recurrent embolic event. These patients are commonly treated with oral anticoagulants, which have the potential for adverse side effects, such as hemorrhaging, hematoma, and interactions with a variety of other drugs. The use of these drugs can alter a person's recovery and necessitate adjustments in a person's daily living pattern.

[0006] In certain cases, such as when anticoagulation is contraindicated, surgery may be necessary or desirable to close the PFO. The surgery would typically include suturing a PFO closed by attaching septum secundum to septum primum. This sutured attachment can be accomplished with either an interrupted or a continuous stitch and is a common way a surgeon shuts a PFO under direct visualization.

[0007] Umbrella devices and a variety of other similar mechanical closure designs, developed initially for percutaneous closure of atrial septal defects (ASDs), have been used in some instances to close PFOs. These devices have the potential to allow patients to avoid the potential side effects often associated with anticoagulation therapies

and the risks of invasive surgery. However, umbrella devices and the like that are designed for ASDs are not optimally suited for use as a PFO closure device.

[0008] Currently available designs of septal closure devices present drawbacks, including technically complex implantation procedures. Additionally, there are not insignificant complications due to thrombus, fractures of the components, conduction system disturbances, perforations of heart tissue, and residual leaks. Many devices have high septal profile and may include large masses of foreign material, which may lead to unfavorable body adaptation of a device. Since ASD devices are designed to occlude a hole, many lack anatomic conformability to the PFO flap-like anatomy. That is, when inserting an ASD device to close a PFO, the narrow opening and the thin flap may form impediments to proper deployment. Even if an occlusive seal is formed, the device may be deployed in the heart on an angle, which could leave some components not securely seated against the septum, thereby risking thrombus formation due to hemodynamic disturbances. Finally, some septal closure devices are complex to manufacture, which may result in lack of consistency in product performance.

[0009] The present invention is designed to address these and other deficiencies of the prior art septal closure devices.

Summary of the Invention

[0010] The present invention provides a device for occluding an anatomical aperture, such as a septal defect or a PFO. This occluder includes two sides connected by an intermediate joint. Each of the sides includes at least one wire or other elongate element for structural support (referred to collectively as "wire"), which is arranged to form non-overlapping loops. Each loop has at least one radially-extending segment that

is adjacent to a radially-extending segment of another loop. In at least some embodiments, at least one pair of adjacent radially-extending segments is connected. The loops of the device may be of various shapes and sizes. In at least some embodiments, the loops have rounded peripheries. The configuration of the loops and sides of the occluder are varied according to different embodiments of the invention. In some embodiments, at least one of the sides includes a tissue scaffold.

[0011] The wires forming the occluders of the present invention may be constructed of various biocompatible materials. In some embodiments, the wires are formed of shape memory materials, *e.g.* nitinol. In other embodiments, the wires are formed of polymers, bioabsorbable polymers, or combinations thereof.

[0012] The occluder according to the present invention is designed such that, when deployed *in vivo*, the two sides are disposed on opposite sides of the septal tissue surrounding the aperture, *i.e.* septum primum and septum secundum. Thus, the two sides exert a compressive force on the septal tissue that is distributed along both the outer periphery of the occluder and the radially-extending segments. In at least some embodiments, the radially-extending segments increase the stiffness of the occluder, thereby preventing the occluder from becoming dislodged from its intended delivery site. In at least some embodiments, the flexible, rounded peripheries of the loops prevent the occluder from inflicting trauma upon the septal tissue as the heart contracts. In at least some embodiments of the present invention, the occluder is repositionable and/or retrievable. These and other advantageous features of the present invention will be explained in more detail in connection with the following illustrations.

Brief Description of the Drawings

[0013] Figures 1 is a schematic representation of a human heart including a septal defect;

[0014] Figure 2 is a top view of an occluder according to one embodiment of the invention;

[0015] Figure 3 is a front elevational view of the distal side of the occluder of Figure 2;

[0016] Figure 4 is a front elevational view of the proximal side of the occluder of Figure 2;

[0017] Figure 5 is a front elevational view of the occluder of Figure 2;

[0018] Figures 6A and 6B are a side view and a front elevational view, respectively, of an occluder according to another embodiment of the present invention;

[0019] Figure 7 is a side elevational view of the occluder of Figures 6A and 6B deployed *in vivo*;

[0020] Figure 8 is a front elevational view of the distal side of an occluder according to a further embodiment of the present invention;

[0021] Figure 9 is a front elevational view of the proximal side of an occluder according to still another embodiment of the present invention;

[0022] Figures 10A-10D are front elevational views of various embodiments of the proximal side of an occluder according to the present invention;

[0023] Figure 11 is a front elevational view of the distal side of an occluder according to yet another embodiment of the present invention;

[0024] Figure 12 is a front elevational view of a proximal side of an occluder according to the present invention that includes a tissue scaffold;

[0025] Figures 13A, 13B, and 13C are perspective, side elevational, and side elevation *in vivo* views, respectively, of an occluder according to yet a further embodiment of the present invention;

[0026] Figures 14A-14E are side elevational views of one method for delivering an occluder according to the present invention to a septal defect;

[0027] Figures 15A-15E are side elevational views of a second method for delivering an occluder according to the present invention to a septal defect;

[0028] Figure 16 is a side elevational view of a partially-deployed occluder according to the present invention;

[0029] Figures 17A-17D are side elevational views of one method for retrieving an occluder according to the present invention from a septal defect; and

[0030] Figure 18 is a side elevational view of a second method for retrieving an occluder according to the present invention from a septal defect.

Detailed Description of the Invention

[0031] The present invention provides a device for occluding an aperture within body tissue. In particular and as described in detail below, the occluder of the present invention may be used for closing a PFO in the atrial septum of a heart. Although the embodiments of the invention are described with reference to a PFO, one skilled in the art will recognize that the device and method of the present invention may be used to treat

other anatomical conditions. As such, the invention should not be considered limited to any particular anatomical condition.

[0032] Figure 1 illustrates a human heart **10**, having a right atrium **11** and a left atrium **13**. The atrial septum **12** includes septum primum **14**, septum secundum **16**, and a passage **18** between the right **11** and left **13** atria. The anatomy of the septum varies widely within the population. In some people, septum primum **14** extends to and overlaps with septum secundum **16**. The septum primum **14** may be quite thin. When a PFO is present, there is a chance that blood could travel through the passage **18** between septum primum **14** and septum secundum **16** (referred to as "the PFO tunnel").

[0033] An occluder according to one embodiment of the present invention is shown in Figures 2 through 7. As shown in Figure 2, the occluder **20** includes a distal side **30** (Figure 3) and a proximal side **40** (Figure 4). In this application, "distal" refers to the direction away from a catheter insertion location and "proximal" refers to the direction nearer the insertion location. Distal side **30** and proximal side **40** are connected by intermediate joint **22**. As shown in Figure 7, the occluder **20** may be inserted into the septal tissue **12** to prevent the flow of blood through the passage **18**, *i.e.* the occluder may extend through the PFO tunnel **18** such that the distal side **30** is located in the left atrium **13** and the proximal side **40** is located in the right atrium **11**. Various features of the occluder **20** will be described with reference to Figures 2 through 7.

[0034] The occluder **20** is constructed of wire or other elongate element for structural support, referred to collectively as "wire" **25**. The wire is arranged to form loops in both the distal **30** and proximal **40** sides of the occluder **20**. According to some embodiments of the present invention, several wires **25** are used to construct the occluder

20. According to other embodiments, the occluder may be formed of a tube using, for example, an etching or cutting process to create elongate members. The elongate members have the general structure of a wire, *i.e.* long and thin, but are not necessarily round. As used herein, the term "wire" is intended to encompass wires and elongate members (whether or not formed by an etched tube).

[0035] The wire(s) **25** may be formed of various biocompatible materials. In at least some embodiments, the occluder **20** is formed of shape memory material (*e.g.* nitinol). The thermal shape memory and/or superelastic properties of shape memory materials, *e.g.* nitinol, permit the occluder **20** to resume and maintain its intended shape *in vivo* despite being distorted during the delivery process. In particular embodiments, the occluder **20** is formed of nitinol that is austenitic at body temperature. Alternatively, or additionally, the occluder **20** may be formed of other high-strength super-alloys, such as Hastelloy® (available from Haynes International), Elgiloy®, or MP35N. In still other embodiments, occluder **20** may be formed of a polymer (*e.g.* plastics), bioabsorbable polymer, or combination of the foregoing.

[0036] The distal side **30** of the occluder **20** (also called the "anchor portion") is shown in Figure 3. The distal side **30** includes three loops **32a**, **32b**, and **32c**, collectively referred to as loops **32**. As illustrated, the loops **32** are evenly distributed about and held together at center joint **22**. Each of loops **32** has six sides of roughly the same linear dimension. Each of loops **32** has at least one segment that is adjacent to a segment of another of loops **32**. Specifically, segment **33a** of loop **32a** is adjacent to segment **31b** of loop **32b**; segment **33b** of loop **32b** is adjacent to segment **31c** of loop **32c**; and segment **33c** of loop **32c** is adjacent to segment **31a** of loop **32a**.

[0037] Although the distal side **30** of the occluder **20** shown in Figure 3 includes three loops **32**, occluders according to the present invention may include any number of loops **32** necessary for a given application. Occluders having less than or equal to ten loops **32** may be formed without requiring significant adjustments. In general, the stiffness of the occluder **20** increases as the number of loops **32** increases. However, occluders having more than ten loops **32** may be complicated to manufacture and deliver through the vasculature. Whatever the number of loops chosen, the loops **32** may be of varied sizes to facilitate delivery, *e.g.* to improve collapsibility of the occluder **20** or to enhance securement at the delivery site. For example, loops **32** sized to better conform with anatomical landmarks will provide enhanced securement of the occluder **20** to the septal tissue **12** *in vivo*.

[0038] Regardless of the number of loops included in distal side **30**, the outer shape of the loops **32** may vary. For example, as illustrated in Figure 3, the loops **32** may be hexagonal with 120 degree angles at their bends (*i.e.* "blunt loops"). Alternatively, or additionally, the non-adjacent wire segments may be rounded to provide for a smoother perimeter. As the number of loops **32** in the distal side **30** of occluder **20** increases, it becomes desirable to round the outer perimeters of the loops **32** so as to prevent the infliction of trauma on the surrounding septal tissue **12**. The loops **32** may also be formed as concave structures, such that the outermost portions of the loops **32** of the distal side **30** oppose the outermost portions of the loops **42** of the proximal side **40**, as described in more detail below, thereby creating a desirable opposing force that secures the occluder **20** at its desired location *in vivo*.

[0039] As previously mentioned, the wires **25** forming loops **32** are attached at center joint **22**. The adjacent segments extend radially outward from center joint **22** at a spacing of approximately 120 degrees apart. The area of septal tissue enclosed by loops **32** provides support for the distal side **30** once the occluder **20** is deployed *in vivo*. In at least one embodiment of the present invention, a connection is provided between the adjacent segments, *e.g.* between segments **33a** and **31b**, between segments **33b** and **31c**, and between segments **33c** and **31a**. For example, as shown in Figure 3, the adjacent segments may be connected by welds **38**. Such connections provide additional stiffness to the occluder **20** and help secure the occluder **20** at its desired location *in vivo*, as described in more detail below.

[0040] The adjacent segments may be connected in a variety of ways. As previously indicated, the adjacent segments may be welded. The length of the welds **38** may extend along less than the entire radial distance of the adjacent segments. Alternatively, the adjacent segments may be connected with a tube, *e.g.* a hypo tube, having a smaller diameter than the diameter of the coupled adjacent segments. In such a configuration, the tube holds the segments together by exerting a compressive force against the wires. Numerous additional means of connecting the segments will be apparent to those skilled in the art, *e.g.* glue, clips, sutures, polymer sleeves, etc., and are considered to be within the scope of the present invention.

[0041] As previously indicated, the connections, *e.g.* welds **38**, between adjacent segments provide stiffness to the distal side **30** of the occluder **20**. As illustrated in Figure 3, the welds **38** may extend a significant distance along the length of the adjacent segments or may extend along only a portion of the adjacent segments. Without

connections between the adjacent segments, a force on any of loops **32** will be borne by that loop alone, and the stiffness of the distal side **30** is diminished. The capacity to vary the stiffness of the distal side **30** using various numbers and types of connections provides significant advantages. Thus, for some applications of the present invention, it may be desirable to include connections between some adjacent segments but not others or to vary the radial distance that the connections extend and/or the placement of the connections relative to the center joint **22**. As the distance that the connections, *e.g.* welds **38**, extend increases, the distal side **30** becomes stiffer. When the connections extend along less than half of the radial distance, the stiffness of the distal side **30** is diminished. The location of welds **38** also affects the stiffness of the occluder **50**. For example, a shorter weld **38** placed at a more radially outward location along the adjacent segments will increase the stiffness and dislodgement resistance of the occluder **20**. In at least some embodiments of the present invention, the connections, *e.g.* welds **38**, extend along the entire length of the adjacent segments.

[0042] It should be noted that the inclusion of connections, *e.g.* welds **38**, to increase the stiffness of the distal side **30** necessitates the use of a greater force to maintain the occluder **20** in reduced profile (*i.e.* in delivery configuration). The delivery system for an occluder **20** including distal side **30** having connections, *e.g.* welds **38**, must, therefore, possess greater radial strength to contain such a configuration.

[0043] The proximal side **40** of the occluder **20** is shown in Figure 4. The proximal side **40** includes six loops, **42a-42f**, collectively referred to as loops **42**. The loops **42** are evenly distributed about tip **44**. Tip **44** may be a weld, solder, or tube into which the wires would fit. Each of loops **42** is formed of wire segments that extend

radially outward from tip **44**, bend approximately 180 degrees, and then extend back to intermediate joint **22**. Thus, one end of each of loops **42** is attached to tip **44**, while the other end of each of loops **42** is attached to intermediate joint **22**. As a result, the axial position of each of loops **42** in proximal side **40** is slightly offset.

[0044] The wires forming each of loops **42** do not overlap, *i.e.* they are not intertwined or weaved. In at least one embodiment, illustrated in Figure 5, the radially-extending segments of the proximal side **40** are rotated, for example, 60 degrees with respect to the radially-extending segments of the distal side **30**. Thus, as shown in Figure 5, the proximal radially-extending segments **41a**, **43b**, **41c**, **43d**, **41e**, and **43f**, which depart from intermediate joint **22** are rotated 60 degrees (as indicated by angle φ) with respect to distal radially-extending segments **31a, 33a, 31b, 33b, 31c,** and **33c**. Further, the loops **42** of proximal side **40** may be flat, while the loops **32** of distal side **30** may be concave, as previously described. Upon deployment *in vivo*, the opposing compressive forces exerted by the sides **30** and **40** on the septal tissue **12** are particularly advantageous.

[0045] Although the proximal side **40** of the occluder **20** shown in Figure 4 includes six loops **42**, one skilled in the art will recognize that the proximal side **40** of an occluder according to the present invention may include any number of loops **42** required for a given application. However, in view of the fact that the loops **42** are non-overlapping, it may not be practical to include more than ten loops **42** in proximal side **40**.

[0046] In a manner similar to that described above with regard to the distal side **30**, loops **42** of proximal side **40** also include adjacent segments that may be connected.

Specifically, segment **43a** of loop **42a** is adjacent to segment **41b** of loop **42b**; segment **43b** of loop **42b** is adjacent to segment **41c** of loop **42c**; segment **43c** of loop **42c** is adjacent to segment **41d** of loop **42d**; segment **43d** of loop **42d** is adjacent to segment **41e** of loop **42e**; segment **43e** of loop **42e** is adjacent to segment **41f** of loop **42f**; and segment **43f** of loop **42f** is adjacent to segment **41a** of loop **42a**. Connections may be included between any or all of the adjacent segments. The adjacent segments may be connected using any of the connection means previously described, *e.g.* welds **48**. For example, as shown in Figure 4, welds **48** are located between each pair of adjacent segments. Alternatively, as shown in Figure 9, welds **98** are located between adjacent segments that are spaced 120 degrees apart, *i.e.* between segments **43b** and **41c**, between segments **43d** and **41e**, and between segments **43f** and **41a**. In preferred embodiments, welds are typically located on those adjacent segments extending from intermediate joint **22**, such that the segments contacting the septal tissue **12** in the right atrium **11** are stiffest. Furthermore, including connections between at least those adjacent segments that contact the septal tissue minimizes fretting and the possibility of corrosion due to metal rubbing against metal.

[0047] As indicated previously and shown in Figure 2, distal side **30** and proximal side **40** of occluder **20** are connected by intermediate joint **22**. The intermediate joint **22** secures the wires of the device and, according to some embodiments, may be a weld, solder or tube. If a tube is used, the tube may have a diameter slightly less than that of the collected wires, such that the tube may be expanded during delivery and then returned to its reduced diameter following deployment of the occluder **20** *in vivo*. The reduced diameter tube will secure the wires forming loops **32** and **42** into the tube. A tube capable

of expanding and reducing may be constructed of a shape memory material, *e.g.* nitinol. Alternatively, the intermediate joint **22** may be a tube having a diameter larger than that of the collected wires; following deployment of the occluder **20** *in vivo*, this tube may be crimped to secure the wires forming loops **32** and **42**.

[0048] In other embodiments of the present invention, the intermediate joint **22** may be a spring, *e.g.* a coil spring. According to these embodiments, the spring is designed to pull the proximal side **40** of occluder **20** closer to the distal side **30**, thereby compressing the septal tissue **12** between the distal **30** and proximal **40** sides *in vivo*. The tension of the spring may be selected such that the occluder **20** accommodates septal tissue of varying thicknesses. When considering the characteristics of the spring, the need to accommodate septal tissue of varying thicknesses and the need to provide sufficient (but not too much) compressive force must be balanced. One skilled in the art will be capable of selecting a spring meeting these criteria for a given application.

[0049] In still further embodiments of the present invention, intermediate joint **22** is positioned at an angle θ, as shown in Figure 6. Often, anatomical anomalies have non-perpendicular apertures and are sometimes quite significantly non-perpendicular. Thus, the occluder **20** may include an angled intermediate joint **22**, such that the angle of the anatomical aperture is more closely matched by the pre-formed angle θ of the occluder **20**. Accordingly, the distal **30** and proximal **40** sides of occluder **20** are more likely to be seated against and minimize distortion to the septal tissue **12** surrounding the passage **18**. A well-seated occluder **20** is less likely to permit blood leakage between the right **11** and left **13** atria, and the subject into which the occluder **20** has been placed is, therefore, less likely to suffer embolisms and other adverse events. Advantageously, angled

intermediate joint **22** also facilitates delivery of occluder **20**, as described in more detail below, because it is angled toward the end of the delivery catheter. In at least some embodiments, the angle θ is about 0-45 degrees off the plane created by the proximal side **40**. One skilled in the art will recognize that the concept of an angled intermediate joint may also be applied to septal occluders other than those disclosed herein.

[0050] When intermediate joint **22** is positioned at angle θ, distal side **30** and proximal side **40** of occluder **20** may be configured such that they are either directly opposing or, as shown in Figures 6A and 6B, offset by distance **A**. One skilled in the art will, of course, recognize that the configuration of either or both of distal side **30** and proximal side **40** may be adjusted such that the compressive forces applied by the distal **30** and proximal **40** sides of occluder **20** are as directly opposing as possible. However, in some clinical applications, an occluder **20** having an offset of distance **A** may be particularly desirable. For example, as shown in Figure 7, if the septal tissue **12** surrounding passage **18** includes a disproportionately thick portion (*e.g.* septum secundum **16** as compared to septum primum **14**), the offset may be used to seat occluder **20** more securely upon septal tissue **12**. Moreover, the offset **A** allows each of sides **30** and **40** to be centered around each side of an asymmetric defect.

[0051] When an intermediate joint **22** at angle θ is included in occluder **20**, a marker is required to properly orient the occluder **20** in its intended *in vivo* delivery location. For example, platinum wire may be wrapped around one of loops **32** or **42** so as to permit visualization of the orientation of the occluder **20** using fluoroscopy. Alternatively, other types of markers may be used, *e.g.* coatings, clips, etc. As will be readily understood by one skilled in the art, the orientation of a non-symmetrical occluder

20 during delivery is of great importance. Of course, when a non-symmetrical occluder **20** is used, the periphery of the occluder **20** may be configured such that the clamping force applied by the proximal side **40** is directly opposed to that applied by the distal side **30**.

[0052] Upon deployment *in vivo* (a process described in detail below), an occluder according to the present invention applies a compressive force to the overlapping layers of septal tissue **12**, *i.e.* septum primum **14** and septum secundum **16**. Distal side **30** is seated against the septal tissue **12** in the left atrium **13**; joint **22** extends through passage **18**; and proximal side **40** is seated against the septal tissue **12** in the right atrium **11**. As illustrated in Figures 2, 5, and 7, the proximal **40** and distal **30** sides of occluder **20** overlap significantly, such that septum primum **14** and septum secundum **16** are "sandwiched" between them once the occluder **20** is deployed. The connected, adjacent segments provide a radially-extending compressive force, while the peripheral loops **32** and **42** provide a circumferential compressive force. Thus, the compressive forces are more evenly and more widely distributed across the surface of the septal tissue **12** surrounding the PFO. The unique combination of radially-extending, connected, adjacent segments and peripheral loops **32** and **42**, therefore, provides the occluder **20** with superior dislodgement resistance as compared to prior art devices. As used herein, "dislodgement resistance" refers to the ability of an occluder **20** to resist the tendency of the force applied by the unequal pressures between the right **11** and left **13** atria (*i.e.* the "dislodging force") to separate the occluder **20** from the septal tissue **12**. Generally, a high dislodgement resistance is desirable.

[0053] Moreover, loops **32** and **42** are configured to provide occluder **20** with adequate surface area to seal the PFO. For example, the broad configuration of loops **32** and **42** increases the surface area of occluder **20**. Thus, loops **32** and **42** provide sealing along a large circumference around the passage **18** (*i.e.* the PFO), thereby minimizing the possibility of leakage between the right **11** and left **13** atria.

[0054] While configured to provide sufficient circumferential sealing, loops **32** and **42** are also configured to minimize the trauma they inflict on the septal tissue **12** surrounding the PFO. Specifically, two features of loops **32** and **42** achieve this. First, the peripheries of loops **32** and **42** may be rounded. Second, the peripheries of loops **32** and **42** are formed of a single wire and are, therefore, more flexible than the interiorly-located, connected, adjacent segments, which are formed of two wires. These features minimize the overall trauma inflicted by occluder **20** on the septal tissue **12** surrounding the PFO. Accordingly, occluder **20** has a low compression resistance. As used herein, "compression resistance" refers to the ability of an occluder **20** to resist the lateral compressive force applied by the heart as it contracts during a heartbeat. Generally, an occluder that resists compressive force, *i.e.* has high compression resistance, is undesirable because its rigid configuration may cause trauma to the septal tissue **12**, the right atrium **11**, and/or the left atrium **13**.

[0055] In heretofore known occluder designs, dislodgement resistance must usually be sacrificed in order to improve, *i.e.* minimize, compression resistance. However, the occluder **20** according to the present invention possesses both increased dislodgement resistance and minimized compression resistance. These desirable attributes are achieved by the unique combination of radially-extending, connected,

adjacent segments and peripheral loops **32** and **42** discussed above. The radially-extending, connected, adjacent segments (*i.e.* struts) increase the stiffness and, correspondingly, the dislodgment resistance of the occluder **20**. The atraumatic shape of the peripheral loops **32** and **42** decreases the compression resistance of the occluder **20**. In effect, because the struts are formed of double-stranded wire and the peripheries of the loops **32** and **42** are formed of single-stranded wire, the center of the occluder **20** is twice as strong as its parameter. This, correspondingly, produces the advantageous combination of increased dislodgement resistance and minimized compression resistance in occluder **20**.

[0056] The dislodgement resistance of occluder **20** may be further increased without increasing the compression resistance by the inclusion of additional struts. As illustrated in Figure 8, additional struts **85a-85c**, collectively referred to as additional struts **85**, may be included between loops **32a-32c**, *i.e.* between adjacent segments **33a** and **31b**, **33b** and **31c**, and **33c** and **31a**. Additional struts **85** may be of any suitable diameter, and, according to some embodiments, the diameter of additional struts **85** may vary along their length. For example, the diameter of additional struts **85** may increase as the additional struts **85** extend from intermediate joint **22** to the periphery of loops **32**. Although Figure 8 depicts additional struts **85** between loops **32** of distal side **30**, additional struts **85** may additionally or alternatively be included between loops **42** of proximal side **40** of occluder **20**.

[0057] The configuration of the occluder **20** according to the present invention provides several further advantages. First, broad loops **32** and **42** create a large surface area for occluder **20** and thereby anchor the occluder **20** more securely *in vivo*. In

contrast, many previously known occluders include narrow loops, which afford less surface area for exertion of compressive forces and secure placement of the occluder **20**. Second, the loops **32** and **42** create an occlusion perimeter that likely extends significantly beyond the passage **18**. Third, loops **32** and **42** are non-overlapping, *i.e.* the wires are not intertwined or weaved. This non-overlapping configuration reduces the occurrence of fretting corrosion, which frequently occurs in prior art devices containing overlapping wires.

[0058] Occluder **20** may be modified in various ways. According to some embodiments of the present invention, loops **32** of distal side **30** and loops **42** of proximal side **40** may be formed in a variety of shapes. Four examples are illustrated in Figures 10A-10D. For convenience, only the proximal side **40** of each of these modified embodiments is depicted. However, the distal side **30** of occluder **20** may be similarly modified. The star-shaped pattern **100a** shown in Figure 10A includes four large loops, referred to collectively as loops **102a**. Loops **102a** are centered and approximately equally spaced around tip **44**. Any or all of loops **102a** may include a smaller loop, collectively referred to as loops **104a**, at their radial extent. Smaller loops **104a** may be capable of receiving a suture to facilitate retrieval of the occluder **20**.

[0059] An alternative, diamond pattern **100b** is shown in Figure 10B. Diamond pattern **100b** includes six diamond-shaped loops, referred to collectively as loops **102b**, which are equally spaced around tip **44**. Diamond pattern **100b** is asymmetrically oriented, such that two of loops **102b** extend further in the radial direction than the other loops **102b**. This asymmetry may provide more complete and secure coverage of passage

18 than that provided by a symmetric occluder **20**. The asymmetric pattern **100b** may also facilitate the compact, percutaneous delivery of occluder **20**.

[0060] Still a further alternative, rectangular pattern **100c**, is shown in Figure 10C. Rectangular pattern **100c** includes four rectangular-shaped loops, referred to collectively as loops **102c**, which are equally spaced around tip **44**. Rectangular pattern **100c** provides extended coverage in two directions. Such a rectangular shape may be particularly suited for coverage of certain passages **18**. Loops **102c** may extend further in either the horizontal or vertical direction. As shown in Figure 10C, loops **102c** extend further in the horizontal direction.

[0061] Yet a further alternative, diamond pattern **100d**, is shown in Figure 10D. Diamond pattern **100d** includes four diamond-shaped loops, referred to collectively as loops **102d**. Two of loops **102d** are larger than the other two loops **102d**. Thus, an extended amount of coverage may be provided across the passage **18** in either the horizontal or vertical direction. As shown in Figure 10D, extended coverage is provided in the horizontal direction.

[0062] Of course, distal **30** and proximal **40** sides of occluder **20** may be configured in a combination of shapes and sizes depending on clinical needs presented by a given PFO. If required, the loops **102** in the illustrative patterns provided in Figures 10A-10D, may be rounded. The number of loops in embodiments of either the distal **30** or proximal **40** sides may be varied as necessary. As previously described, loops **102** in the illustrative patterns provided in Figures 10A-10D include adjacent segments, which may be connected by, *e.g.*, welds **108a-108d**, respectively. One skilled in the art will be able to identify the configuration(s) appropriate for a given clinical application.

[0063] According to further embodiments of the present invention, smaller loops may be included on distal side **30** and/or proximal side **40** of occluder **20** to increase the compressive force applied in close proximity to passage **18** (*i.e.* the PFO). As illustrated in Figure 11, three smaller loops **115a-115c**, referred to collectively as smaller loops **115**, are located on distal side **30**. Smaller loops **115** are centered and equally spaced around intermediate joint **22**. Although smaller loops **115a-115c** in Figure 11 correspond in number and alignment with loops **32a-32c**, respectively, such correspondence is not required. Moreover, smaller loops **115** need not lie entirely in the same plane as loops **32** or **42**. Thus, smaller loops **115** may bend in a direction generally perpendicular to the plane in which loops **32** or **42** lie. Smaller loops **115** may be attached only to intermediate joint **22** or, alternatively, may also be connected to the adjacent segments of loops **32**. In still other embodiments, smaller loops **115** may be located at the peripheries of loops **32** rather than connected to intermediate joint **22**. When the smaller loops **115** are located at the peripheries of loops **32**, additional wire segments may be included within loops **32** to connect the smaller loops **115** to the intermediate joint **22**. One skilled in the art will be able to determine the precise configuration of smaller loops **115** appropriate for a given clinical application.

[0064] According to still further embodiments of the present invention and as illustrated in Figure 12, distal side **30** and/or proximal **40** side of occluder **20** may include a tissue scaffold **125**. Tissue scaffold **125** ensures more complete coverage of passage **18** and promotes encapsulation and endothelialization of septal tissue **12**, thereby further encouraging anatomical closure of septum primum **14** and septum secundum **16**. Tissue scaffold **125** may be formed of any flexible, biocompatible material capable of promoting

tissue growth, including but not limited to polyester fabrics, Teflon-based materials, ePTFE, polyurethanes, metallic materials, polyvinyl alcohol (PVA), extracellular matrix (ECM) or other bioengineered material, synthetic bioabsorbable polymeric scaffolds, other natural materials (*e.g.* collagen), or combinations of the foregoing materials. For example, tissue scaffold **125** may be formed of a thin metallic film or foil, *e.g.* a nitinol film or foil, as described in United States Patent Appln. No. 2003/0059640 (the entirety of which is incorporated herein by reference).

[0065] Adjacent segments may be stitched to tissue scaffold **125** so as to securely fasten the scaffold **125** to occluder **20**. For example, Figure 12 shows tissue scaffold **125** affixed to proximal side **40** of an occluder according to the present invention. Proximal side **40** includes six loops **42a-42f**, collectively referred to as loops **42**. Adjacent segments **43a** and **41b**, **43b** and **41c**, **43c** and **41d**, **43d** and **41e**, **43e** and **41f**, and **43f** and **41a** are attached to tissue scaffold **125** by stitches **127**. Stitches **127** increase the stiffness of occluder **20** without welding or soldering. Additionally, when the adjacent segments of loops **42** are connected to tissue scaffold **125**, the adjacent segments of loops **42** may be spaced apart a small distance (*i.e.* they need not necessarily be connected). Altering the spacing of the adjacent segments of loops **42** adjusts the stiffness of the occluder **20**, which may be desirable in certain circumstances. One skilled in the art will be able to determine those clinical applications in which the use of stitches **127** and/or spaced, adjacent segments is appropriate.

[0066] According to yet further embodiments of the present invention, the configuration of occluder **20** may be modified to produce the low-profile occluder **130** shown in Figure 13A. In this embodiment, the manufacturing process is modified to

increase the force with which the distal **30** and proximal **40** sides urge toward one another. Specifically, during manufacture, distal **30** and proximal **40** sides of occluder **20** may be crossed over each other (as shown in Figure 13B) prior to connecting the adjacent segments of loops **32** and **42** (*i.e.* while the occluder **20** is in an "unconstrained" state). This crossed-over configuration may be achieved by, for example, using the shape memory properties of a shape memory material, such as nitinol, *i.e.* forcing, *e.g.*, loops **42d** and **42e** of proximal side **40** through loop **32c** of distal side **30** or vice versa and heat-setting the crossed-over shape. The crossed-over shape, therefore, becomes the predisposed position of occluder **20**. Occluder **20** is then returned to its original, non-crossed-over state, and the adjacent segments of loops **32** and **42** are connected. The connected, adjacent segments prevent loops **42d** and **42e** from passing through loop **32c**, and occluder **20** is, consequently, no longer capable of assuming its predisposed position. However, loops **42d** and **42e** of proximal side **42** still tend to bend toward distal side **30**. The resulting occluder **130**, shown in Figure 13A, is of low profile. Further, occluder **130** exerts a greater compressive force on the septal tissue **12** when deployed *in vivo* (as shown in Figure 13C) then at least some of the previously-described embodiments of occluder **20**. This increased compressive force may be desirable in applications where the septal tissue **12** is particularly thin in one area, *i.e.* septum primum **14**. The profile of occluder **130** may be lowered even further by angling tip **44** such that it is substantially parallel to proximal side **40** of occluder **130**, as shown in Figure 13A. Angled tip **44** also facilitates catheter delivery of occluder **130** because angled tip **44** points toward the end of the delivery catheter.

[0067] Finally, although occluders according to the present invention have been heretofore described as including distal **30** and proximal **40** sides having different configurations, an occluder **20** according to the present invention may, alternatively, include distal **30** and proximal **40** sides having identical configurations. This identical design may provide several advantages, including ease of manufacture. Furthermore, any of the configurations described herein for either distal side **30** or proximal side **40** may be applied to either or both of distal side **30** and proximal side **40** of occluder **20**.

[0068] An occluder as described herein may be delivered to a septal defect using any of several suitable delivery techniques, two of which will be described herein. In the first delivery technique, shown in Figures 14A-14E, a delivery catheter **140** is used to deliver, *e.g.*, occluder **20**. Catheter **140** contains occluder **20** in its distorted, elongated form. As previously mentioned, in at least some embodiments, occluder **20** is formed of a shape memory material, *e.g.* nitinol, such that occluder **20** will resume its intended shape following deployment *in vivo*. As shown in Figure 14A, delivery catheter **140** is first inserted into the right atrium **11** of the subject's heart. Catheter **140** is next inserted between septum primum **14** and septum secundum **16** (*i.e.* through passage **18**, which, in this embodiment, is the PFO tunnel) and into the left atrium **13** (Figure 14B). Distal side **30** of occluder **20** is then deployed into the left atrium **13**, as shown in Figure 14C. Following deployment of distal side **30**, the catheter **140** is withdrawn through the PFO tunnel and into the right atrium **11**, such that intermediate joint **22** is deployed through the PFO tunnel (Figure 14D). Finally, proximal side **40** of occluder **20** is deployed into the right atrium **11**, and catheter **140** is withdrawn from the heart (Figure 14E). Once deployed, occluder **20** rests within the septal defect, and the distal **30** and proximal **40**

sides exert a compressive force against septum primum **14** and septum secundum **16** in the left **13** and right **11** atria, respectively, to close the PFO.

[0069] In a second delivery technique, shown in Figures 15A-15E, delivery catheter **150** includes a needle **151** capable of puncturing septum primum **14**. As illustrated in Figure 15A, septum primum **14** is long and thin and extends over septum secundum **16** in the left atrium **13**. In some clinical applications, it may be advantageous to access the left atrium **13** by puncturing septum primum **14** rather than inserting the occluder **20** through the passage **18** between septum primum **14** and septum secundum **16**. For example, some anatomical configurations include an extremely oblique passage **18** between the right atrium **11** and the left atrium **13**. Thus, according to this second delivery technique, delivery catheter **150** includes a needle **151** on its distal end and contains occluder **20** in its distorted, elongated form. Catheter **150** is first inserted into the right atrium **11** of the subject's heart (Figure 15A). Next, as shown in Figure 15B, needle **151** punctures septum primum **14**, and catheter **150** enters the left atrium **13**. Needle **151** is then retracted, and distal side **30** of occluder **20** is deployed into the left atrium **13** (Figure 15C). Following deployment of distal side **30**, catheter **150** is withdrawn through septum primum **14** and into the right atrium **11**, such that intermediate joint **22** is deployed through septum primum **14**, as shown in Figure 15D. Finally, proximal side **40** of occluder **20** is deployed into the right atrium **11**, and catheter **150** is withdrawn from the heart (Figure 15E). Once deployed, the distal **30** and proximal **40** sides of occluder **20** exert a compressive force against septum primum **14** and septum secundum **16** in the left **13** and right **11** atria, respectively, to close the PFO. When using this second delivery technique to deploy occluder **20**, intermediate joint **22** should not be

angled, *i.e.* intermediate joint **22** should be perpendicular to both the distal **30** and proximal **40** sides of the occluder **20**.

[0070] Figure 16 provides a more detailed representation of occluder **20** in its intermediate configuration between its compressed and fully-deployed states. As previously described, proximal side **40** of occluder **20** includes wire(s) **25**, which form connected, adjacent radially-extending segments and loops **42**, and tip **44**. During delivery of occluder **20**, tip **44** is attached to a delivery wire **161**, in a manner known to those skilled in the art. When the proximal side **40** of occluder **20** is being deployed in the right atrium **11**, the wire(s) **25** exit catheter **140** or **150** first, followed by tip **44**, and, finally, delivery wire **161**. Once occluder **20** has been positioned, delivery wire **161** is then fully retracted into the catheter **140** or **150** and the catheter is retracted out of the right atrium **11**.

[0071] Delivery wire **161** may be used to reposition and/or retrieve occluder **20** as shown in Figures 17A-17D. If, following partial or complete deployment, the clinician desires to reposition or retrieve occluder **20**, tip **44** may be recaptured with delivery wire **161** in catheter **170**, as shown in Figure 17A. As delivery wire **161** and tip **44** are pulled back into catheter **170**, loops **42** of proximal side **40** fold back into their delivery (*i.e.* compressed) configuration (Figure 17B) and are constrained by catheter **170**. Catheter **170** is then advanced through passage **18** and delivery wire **161** is further retracted, such that loops **32** of distal side **30** fold into their delivery configuration (Figure 17C) and are constrained by catheter **170**. Catheter **170** containing retrieved occluder **20** is then withdrawn through passage **18**, into the right atrium **11** (Figure 17D), and out of the heart.

[0072] In some embodiments according to the present invention, occluder **20** may be repositioned and/or retrieved using the alternative technique shown in Figure 18. As previously described, an occluder **20** according to the present invention may include identical distal **30** and proximal **40** sides. Thus, for example, occluder **20** may include both distal **30** and proximal **40** sides as depicted in Figure 3. In such an embodiment, proximal side **40** will not include a tip **44** for recovery by a delivery wire. An alternative method of retrieving the occluder is, therefore, required. In Figure 18, occluder **20** has been delivered (according to either of the delivery techniques described above) to the extent that proximal side **40** has been deployed in the right atrium **11** but not released from catheter **140**. A thread **181**, such as a suture, is attached to each of loops **42** on proximal side **40** of occluder **20**. If the occluder **20** requires repositioning, then thread **181** may be retracted and loops **42** will fold back into their delivery configuration, such that occluder **20** may be repositioned or, even, completely retrieved. Once occluder **20** has been deployed correctly, thread **181** may be cut and removed via catheter **140**.

[0073] One skilled in the art would recognize that the occluders described herein may be used with anti-thrombogenic compounds, including but not limited to heparin and peptides, to reduce thrombogenicity of the occluder and/or to enhance the healing response of the septal tissue **12** following deployment of the occluder *in vivo*. Similarly, the occluders described herein may be used to deliver other drugs or pharmaceutical agents (*e.g.* growth factors, peptides). The anti-thrombogenic compounds, drugs, and/or pharmaceutical agents may be included in the occluders of the present invention in several ways, including by incorporation into the tissue scaffold **125**, as previously described, or as a coating, *e.g.* a polymeric coating, on the wire(s) forming the distal **30**

and proximal **40** sides of the occluder. Furthermore, the occluders described herein may include cells that have been seeded within tissue scaffold **125** or coated upon the wire(s) forming the distal **30** and proximal **40** sides of the occluder.

[0074] One skilled in the art would recognize that occluders according to this invention could be used in occluding other vascular and non-vascular openings. For example, the device could be inserted into a left atrial appendage or other tunnels or tubular openings within the body.

[0075] Having described preferred embodiments of the invention, it should be apparent that various modifications may be made without departing from the spirit and scope of the invention, which is defined in the claims below.

We claim:

1. A medical device for occluding an anatomical aperture, comprising a plurality of elongate elements, wherein the elements are arranged to form non-overlapping loops such that each loop has at least one segment adjacent to a segment from another loop and wherein at least one pair of adjacent segments are connected to each other.

2. The medical device of claim 1, wherein said at least one connected pair of adjacent segments comprise radially-extending segments.

3. The medical device of claim 2, wherein said at least one connected pair of adjacent segments are welded.

4. The medical device of claim 2, wherein said plurality of elongate elements form at least two loops.

5. The medical device of claim 2, wherein said plurality of elongate elements form at least four loops and at least three pairs of adjacent segments are connected to each other.

6. The medical device of claim 2, wherein each of said non-overlapping loops forms part of the outer periphery of the device.

7. The medical device of claim 6, wherein each of said non-overlapping loops includes a rounded edge at its periphery.

8. The medical device of claim 7, wherein the outer periphery is a circle.

9. The medical device of claim 1, wherein said device includes a material selected from the group consisting of metals, shape memory materials, alloys, polymers, bioabsorbable polymers, and combinations thereof.

10. The medical device of claim 9, wherein said device includes nitinol.

11. The medical device of claim 1, wherein said elongate element includes wire.

12. The medical device of claim 1, wherein said device is machined from a single tube.

13. A device for occluding a defect in septal tissue, comprising:

a first side adapted to be disposed on one side of septal tissue with a defect and a second side adapted to be disposed on an opposite side of the septal tissue with a defect,

said first and second sides adapted to occlude the defect upon deployment at the delivery location,

said first and second sides each comprising a plurality of non-overlapping wires, wherein said wires form loops that extend from a center axis and adjacent segments of said loops are connected to each other.

14. The device of claim 13, wherein said device is adapted to center around an asymmetrically-located defect.

15. The device of claim 13, wherein said adjacent segments are welded.

16. The device of claim 13, wherein said device includes a material selected from the group consisting of metals, shape memory materials, alloys, polymers, bioabsorbable polymers, and combinations thereof.

17. The device of claim 16, wherein said device includes nitinol.

18. The device of claim 13, wherein at least one of said first and second sides further comprises a tissue scaffold.

19. The device of claim 18, wherein said tissue scaffold includes a material selected from the group consisting of polyester fabrics, Teflon-based materials, polyurethanes, metals, polyvinyl alcohol (PVA), extracellular matrix (ECM) or other bioengineered material, synthetic bioabsorbable polymeric scaffolds, collagen, and combinations thereof.

20. The device of claim 19, wherein said tissue scaffold includes nitinol.

21. The device of claim 19, wherein said tissue scaffold is attached to said loops of said at least one side.

22. The device of claim 13, wherein said first and second sides are connected by an intermediate joint.

23. The device of claim 22, wherein said intermediate joint is positioned so as to minimize distortion to the septal tissue surrounding the defect.

24. The device of claim 23, wherein said intermediate joint is positioned at an angle θ from said second side and wherein said angle θ is greater than 0 degrees and less than about 90 degrees.

25. A device for occluding a defect in septal tissue, comprising:

a first side adapted to be disposed on one side of the septal tissue with a defect and a second side adapted to be disposed on an opposite side of the septal tissue with a defect,

said first and second sides adapted to occlude the defect upon deployment at the delivery location,

said first and second sides each comprising a plurality of non-overlapping wires, wherein said wires form loops that extend generally radially from a center axis and include circumferential wire segments, and

wherein said radially-extending wire segments and said circumferential wire segments cooperate to provide a compressive force to the septal tissue surrounding the defect.

26. The device of claim 25, wherein said first and second sides comprise wire loops.

27. The device of claim 26, wherein each of said first and second sides comprises at least three adjacent loops.

28. The device of claim 27, wherein said radially-extending wire segments of said at least three adjacent loops are connected.

29. The device of claim 28, wherein said radially-extending wire segments of said at least three adjacent loops are welded.

30. The device of claim 28, wherein said compressive force exerted by said radially-extending wire segments of said adjacent loops is at least twice as great as that exerted by said circumferential wire segments of said adjacent loops.

31. The device of claim 25, wherein said device further comprises an intermediate joint connecting said first and second sides.

32. The device of claim 31, wherein said intermediate joint is positioned so as to minimize distortion to the septal tissue surrounding the defect.

33. The device of claim 32, wherein said intermediate joint is positioned at an angle θ from said second side and wherein said angle θ is greater than 0 degrees and less than about 90 degrees.

34. The device of claim 25, wherein said device includes a material selected from the group consisting of metals, shape memory materials, alloys, polymers, bioabsorbable polymers, and combinations thereof.

35. The device of claim 34, wherein said device includes nitinol.

36. The device of claim 25, wherein at least one of said first and second sides further comprises a tissue scaffold.

37. The device of claim 36, wherein said tissue scaffold includes a material selected from the group consisting of polyester fabrics, Teflon-based materials, polyurethanes, metals, polyvinyl alcohol (PVA), extracellular matrix (ECM) or other bioengineered material, synthetic bioabsorbable polymeric scaffolds, collagen, and combinations thereof.

38. The device of claim 37, wherein said tissue scaffold includes nitinol.

39. The device of claim 36, wherein said tissue scaffold is attached to said loops of said first and second sides.

40. A medical device for occluding an anatomical aperture, comprising a plurality of elongate members,

wherein said elongate members are arranged to form non-overlapping loops such that each loop has at least one segment adjacent to a segment from another loop,

wherein at least one pair said adjacent segments are connected to each other, and

a reinforcing element is associated with said adjacent segments.

41. The medical device of claim 35, wherein said elongate members are wires and at least one connected pair of adjacent segments comprise radially-extending segments.

42. The medical device of claim 41, wherein said at least one connected pair of adjacent segments are welded.

43. The medical device of claim 41, wherein said plurality of wires form at least two loops.

44. The medical device of claim 41, wherein said plurality of wires form at least four loops and at least three pairs of adjacent wire segments are connected to each other.

45. The medical device of claim 40, wherein a part of each of said non-overlapping loops forms part of the outer periphery of the device.

46. The medical device of claim 45, wherein each of said non-overlapping loops includes a rounded edge at its periphery to minimize trauma to tissue.

47. The medical device of claim 46, wherein the outer periphery is a circle.

48. The device of claim 40, wherein said device includes a material selected from the group consisting of metals, shape memory materials, alloys, polymers, bioabsorbable polymers, and combinations thereof.

49. The device of claim 48, wherein said device includes nitinol.

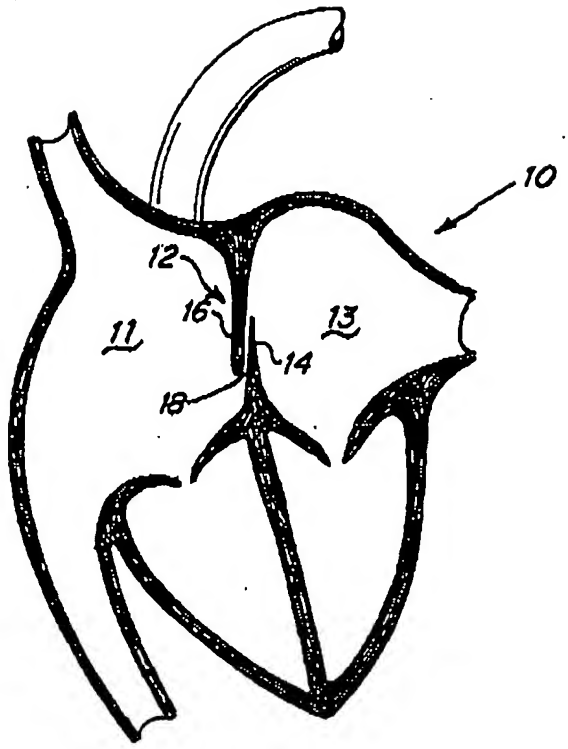


Fig. 1

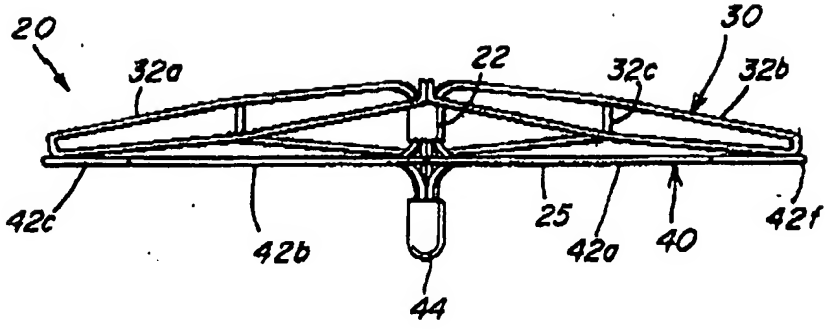


Fig. 2

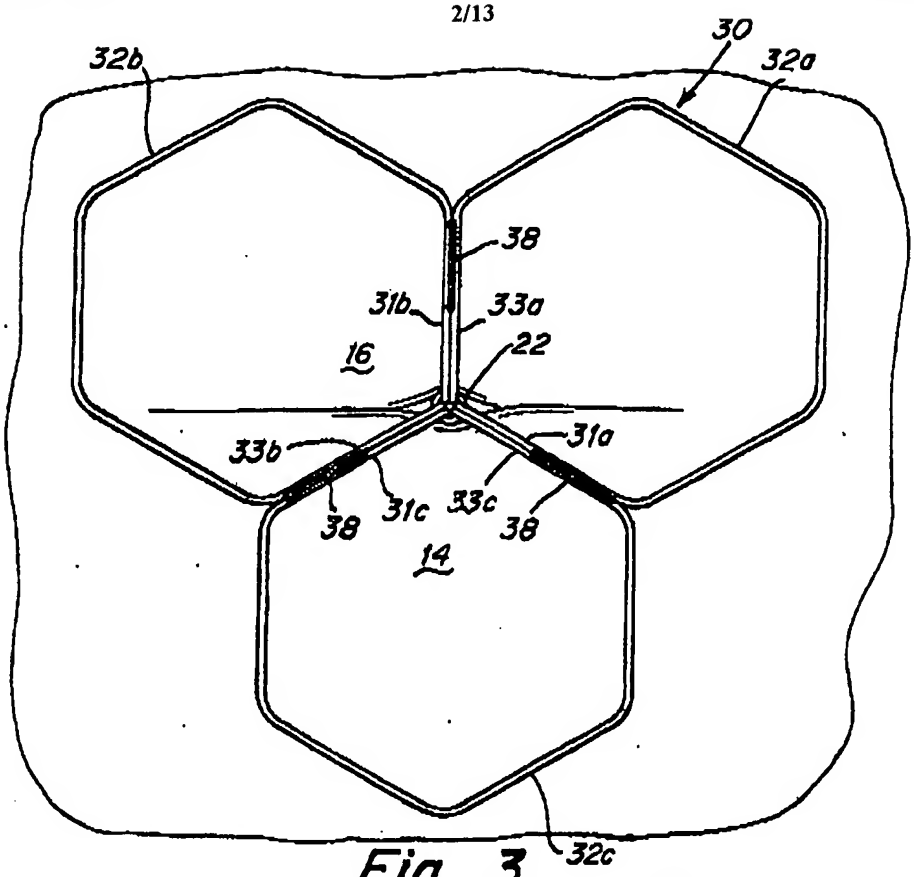
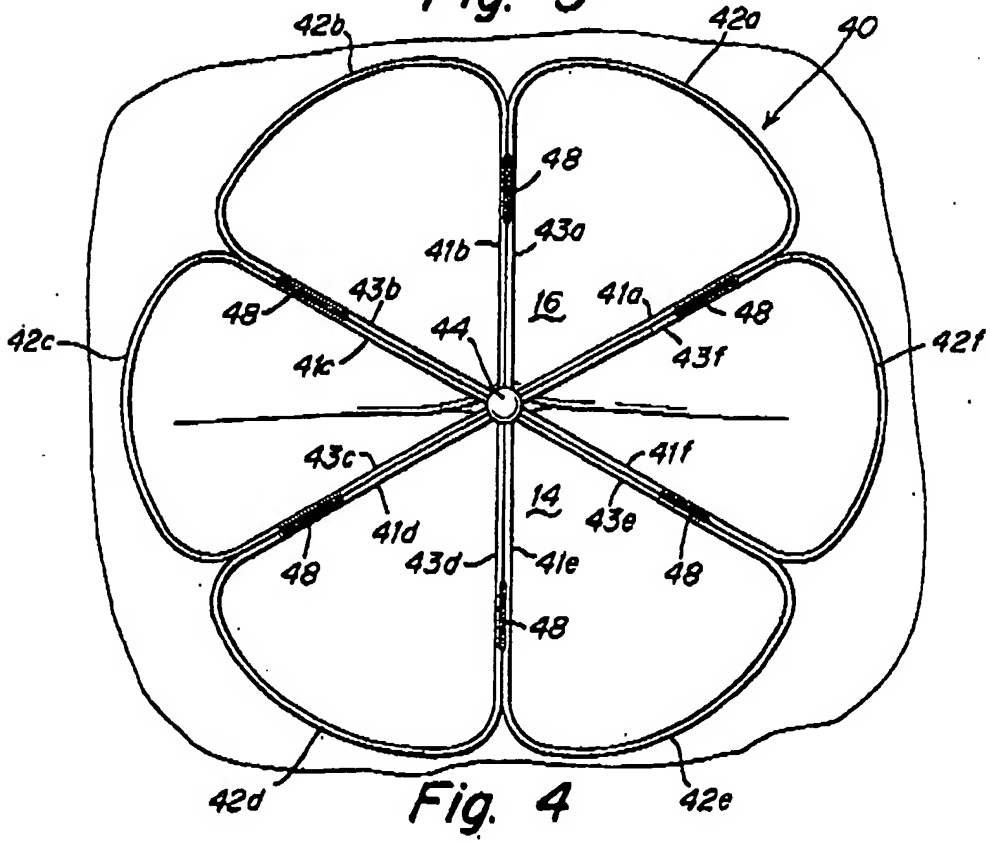

30
32b
32a
38
31b
33a
16
22
33b
31a
38
31c
33c
38
14
32c

Fig. 3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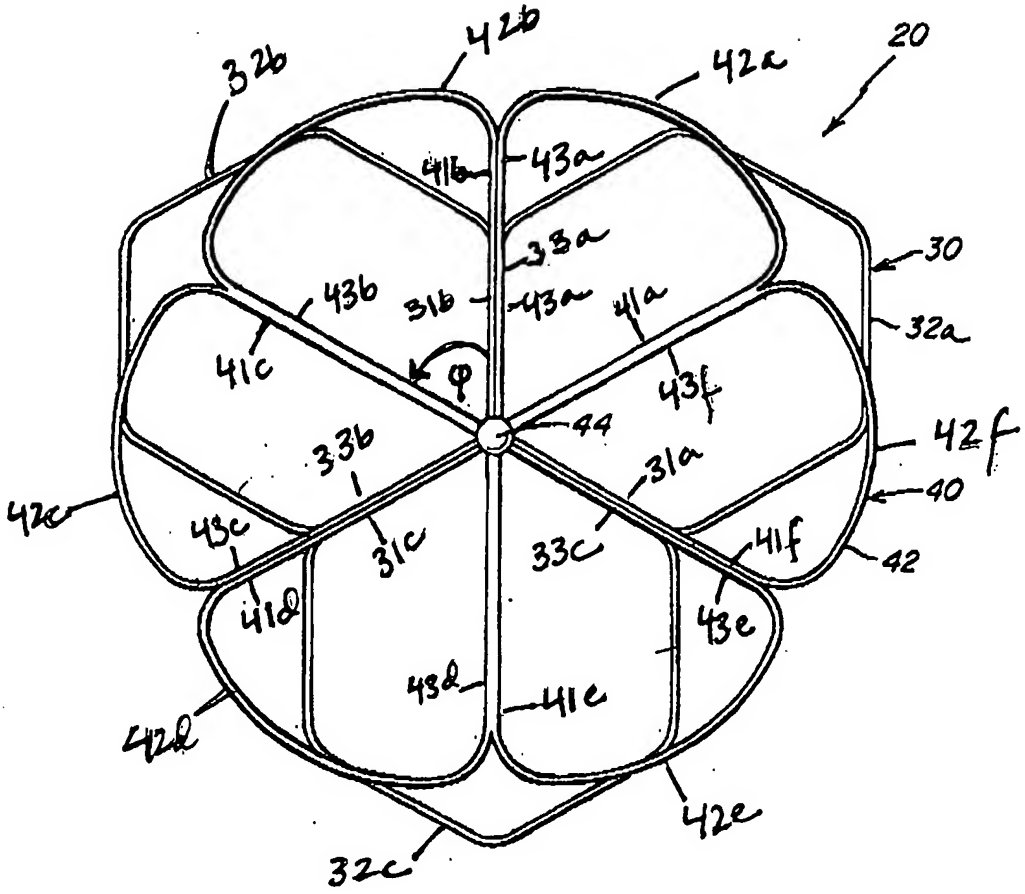
42d
42e

Fig. 4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42f
33b
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43d
41c
42d
42e
32c

Fig. 5

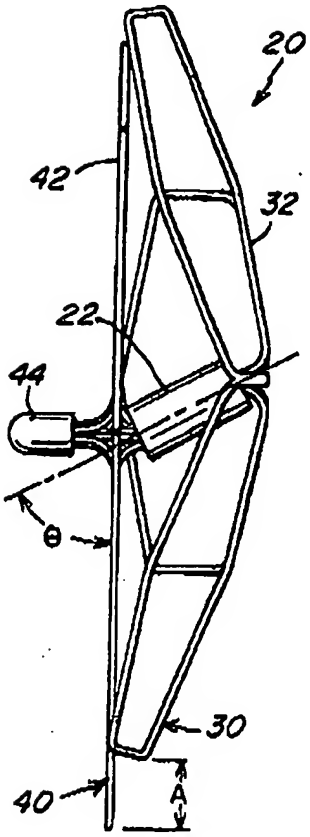


Fig. 6A

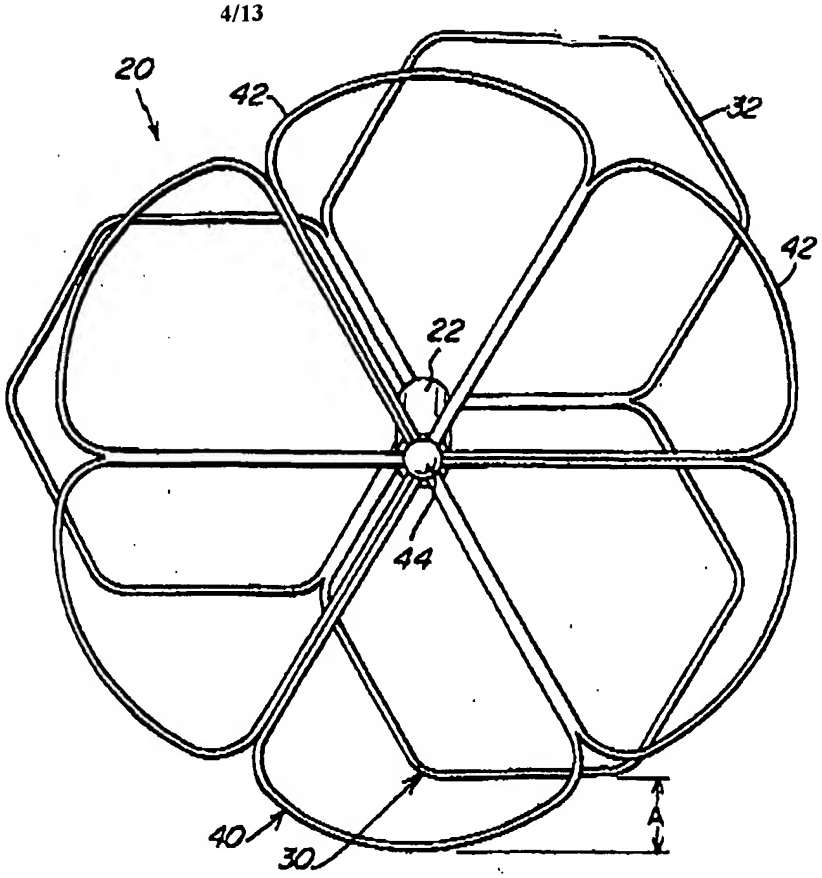


Fig. 6B

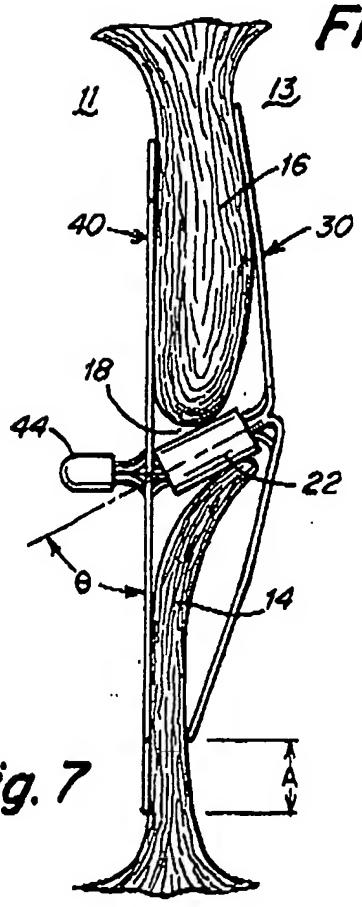
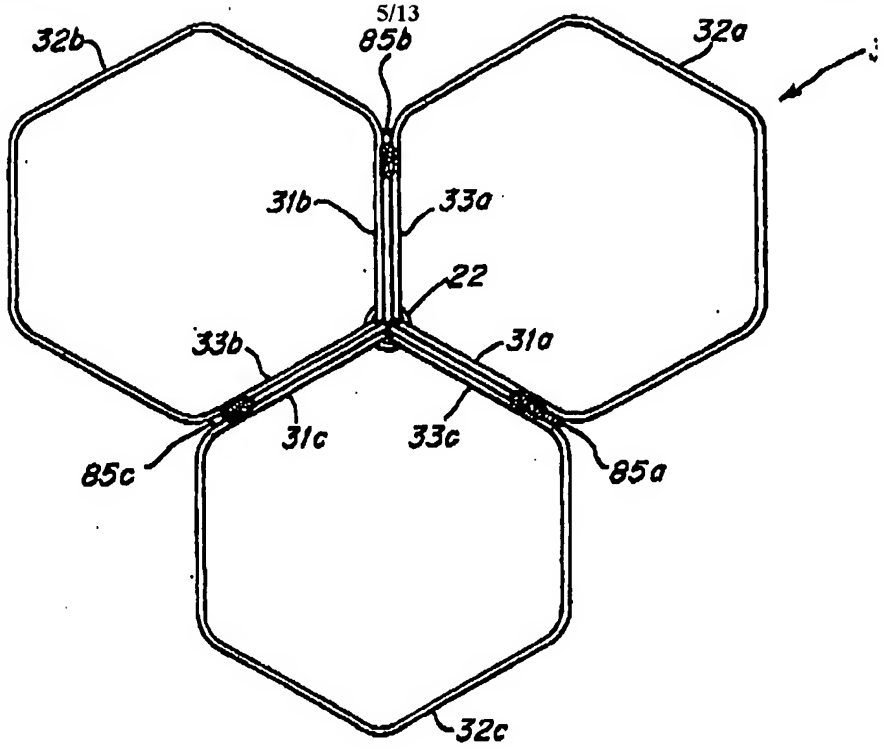


Fig. 7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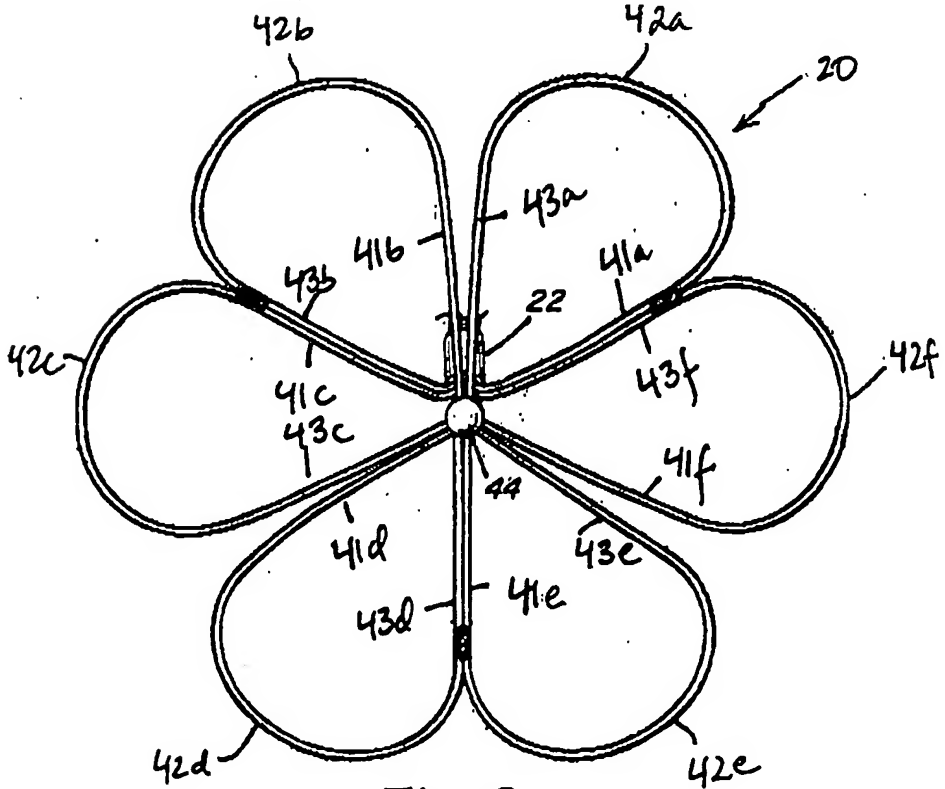
85c
85a
32c

Fig. 8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43d
41e
42d
42e

Fig. 9

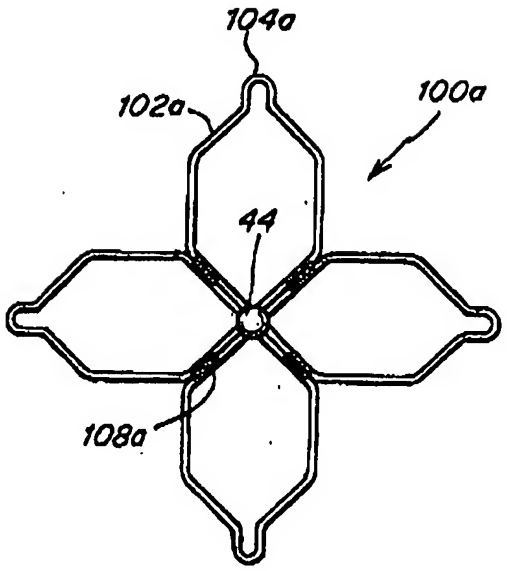


Fig. 10A

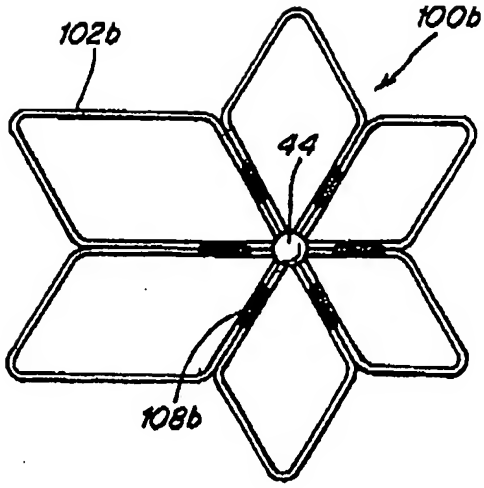


Fig. 10B

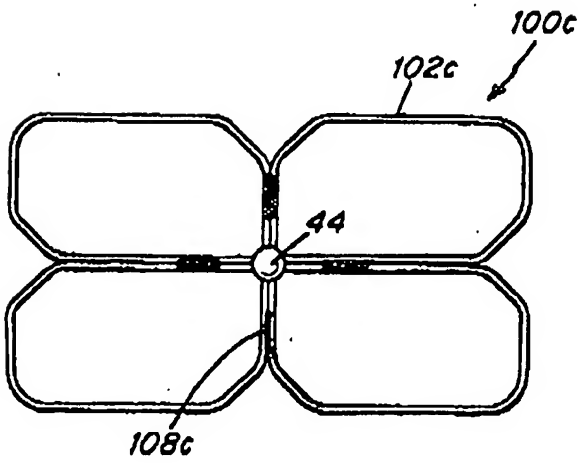


Fig. 10C

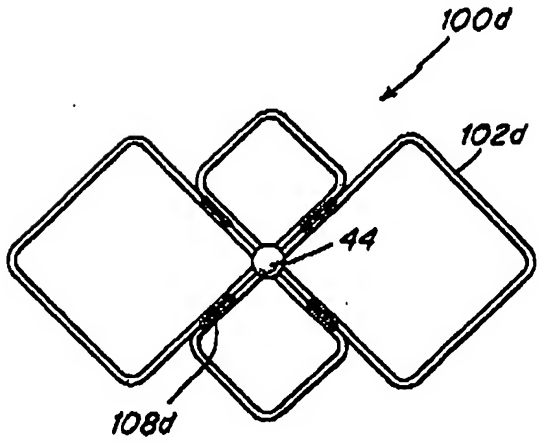
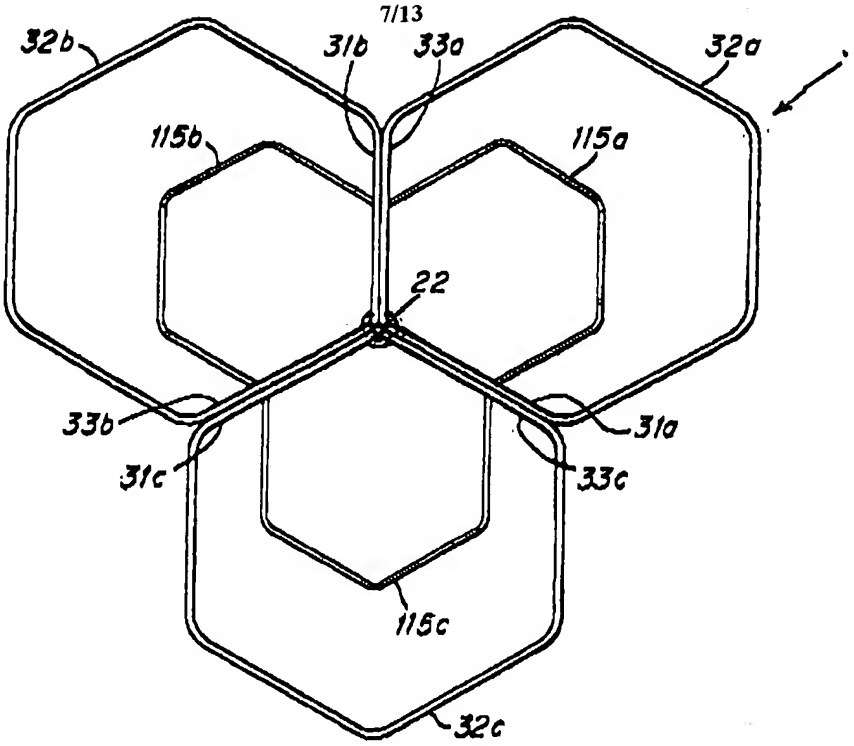


Fig. 10D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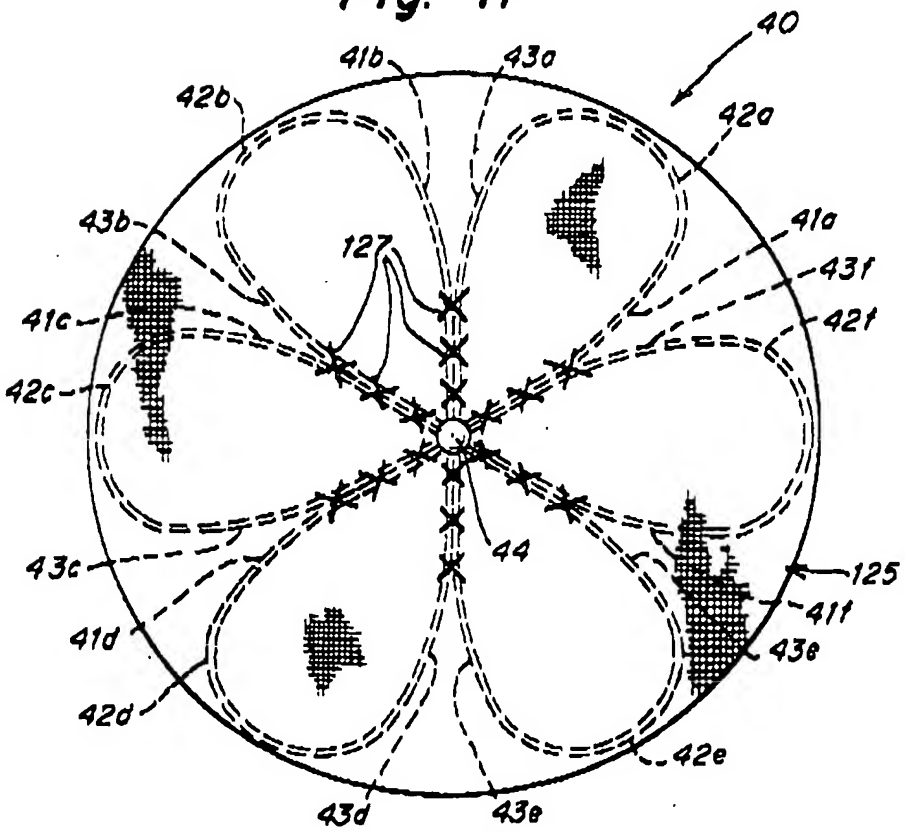
115c
32c

Fig. 11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42e
43d
43e

Fig. 12

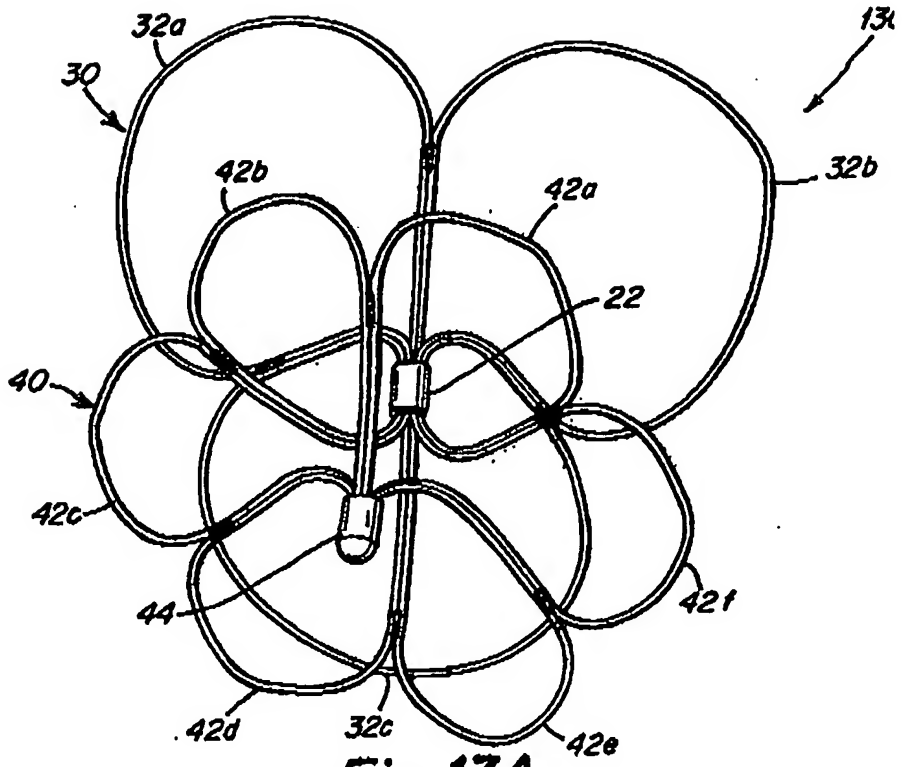

Fig. 13A

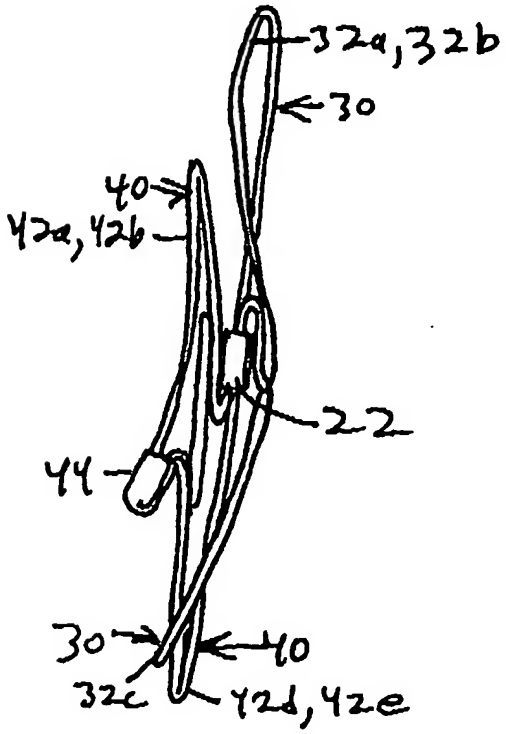

Fig. 13B

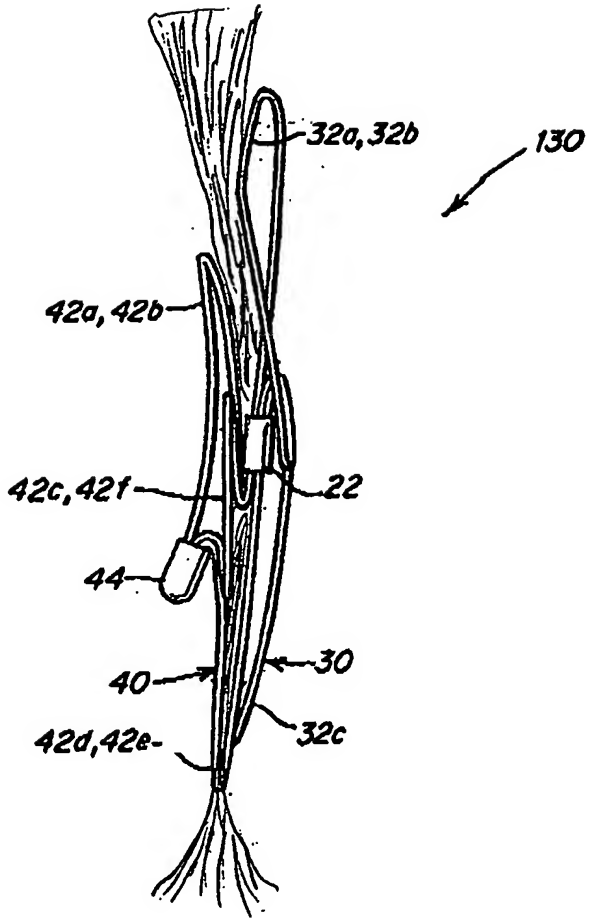

Fig. 13C

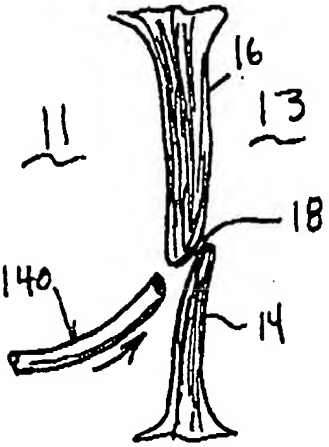

Fig. 14A

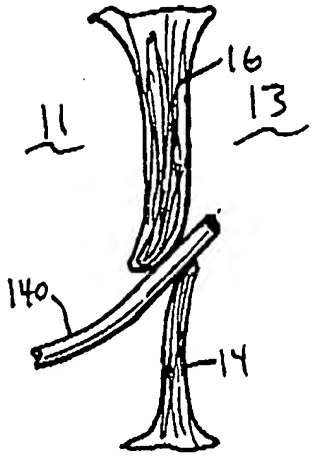

Fig. 14B

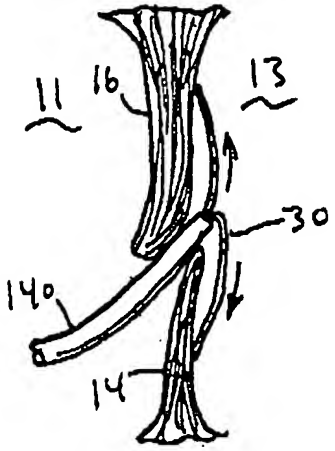

Fig 14C

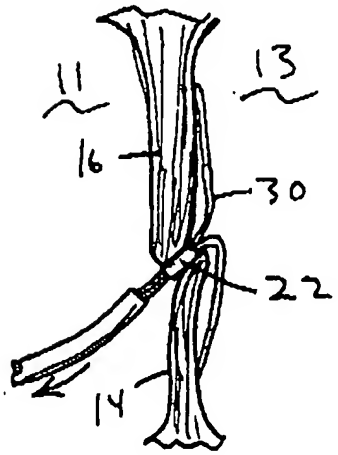

Fig 14D

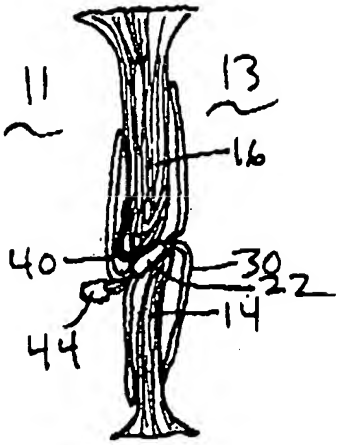

Fig 14E

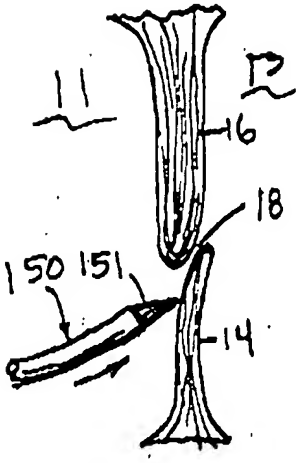

Fig. 15A

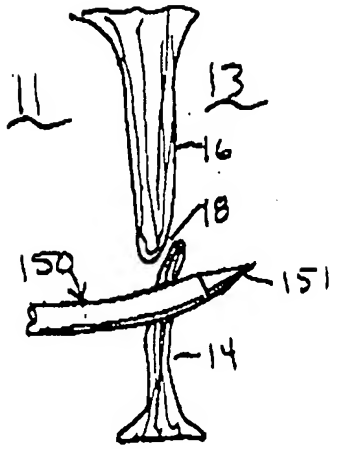

Fig. 15B

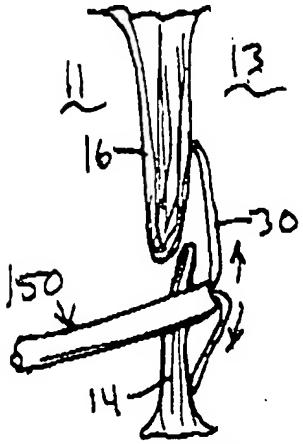

Fig 15C

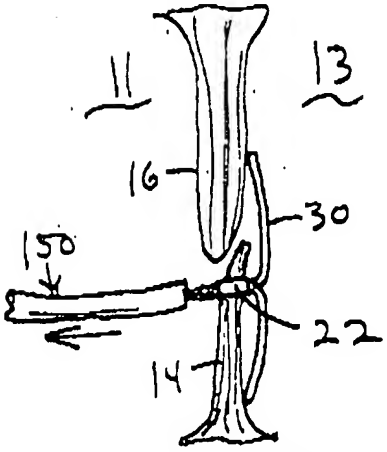

Fig 15D

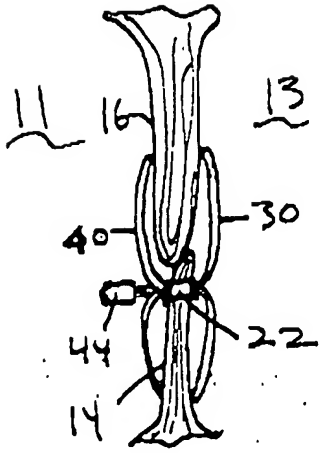

Fig. 15E

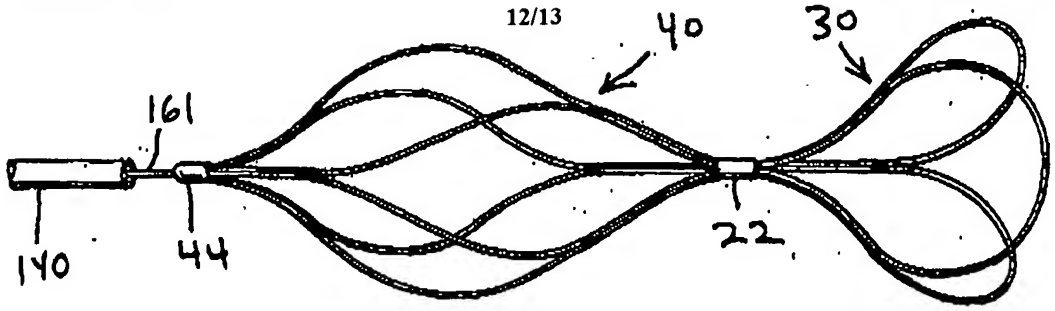

Fig. 16

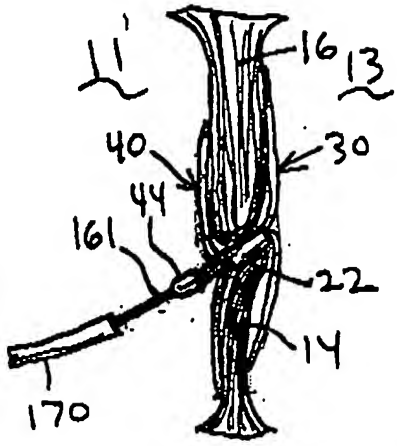

Fig. 17A

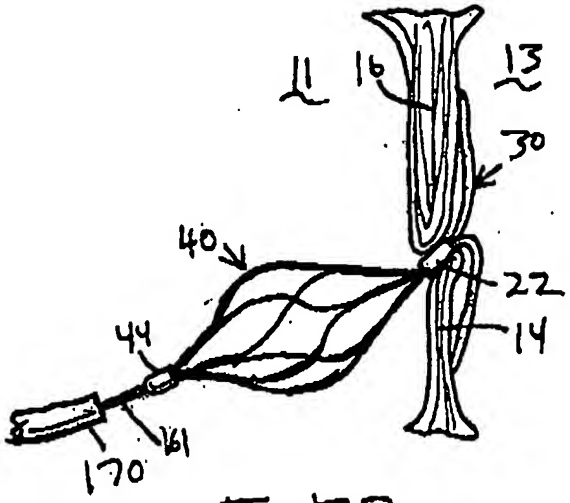

Fig. 17B

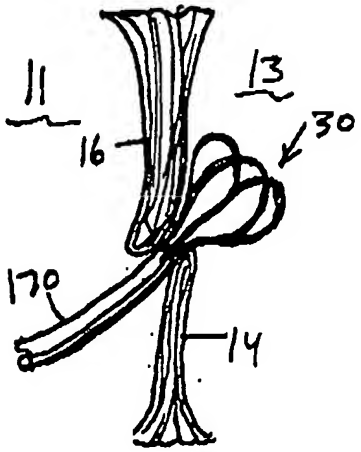

Fig. 17C

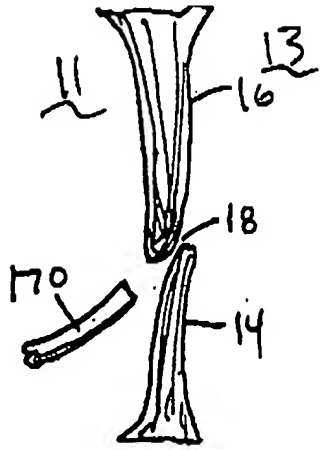

Fig. 17D

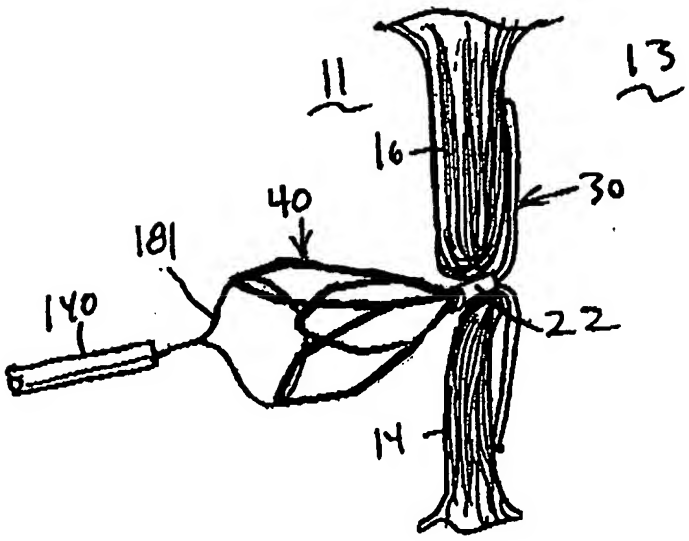

Fig. 18

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 November 2003 (20.11.2003)

PCT

(10) International Publication Number
WO 03/094742 A1

(51) International Patent Classification[7]: A61B 17/00, 17/04

(21) International Application Number: PCT/US03/13970

(22) International Filing Date: 5 May 2003 (05.05.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/138,565 6 May 2002 (06.05.2002) US

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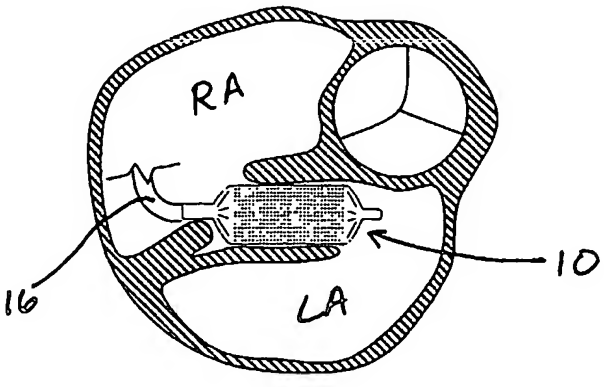
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PFO CLOSURE DEVICES AND RELATED METHODS OF USE



(57) Abstract: Devices and methods for sealing a passageway formed by a patent foramen ovale (PFO track) in the heart are provided. Devices are provided which can be placed into the PFO track to apply adhesive to the walls of the PFO track. The devices may or may not be left within the PFO track. If the devices are not left within the PFO track, the walls of the PFO track, covered with adhesive, are brought into apposition with one another and adhered together. If the device is left within the PFO track, the device is flattened from an expanded configuration to a flattened configuration, and the walls of the PFO track, adhering to the outer surface of the device, are pulled toward each other as the device flattens. The device may also include interior structure to hold the device in a flattened configuration.

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PFO CLOSURE DEVICES AND RELATED METHODS OF USE

DESCRIPTION OF THE INVENTION

Field of the Invention

[001] This invention relates to devices for closing a passageway in a body, for example a patent foramen ovale in a heart, and related methods of using such closure devices for sealing the passageway.

Background of the Invention

[002] Fig. 1 shows a short-axis view of the heart at the level of the right atrium (RA) and left atrium (LA), in a plane generally parallel to the atrio-ventricular groove, and at the level of the aortic valve. This view is looking from caudal to cranial. Fig. 1 also shows the septum primum (SP), a flap-like structure, which normally covers the foramen ovale, an opening in the septum secundum (SS) of the heart. In utero, the foramen ovale serves as a physiologic conduit for right-to-left shunting of blood in the fetal heart. After birth, with the establishment of pulmonary circulation, the increased left atrial blood flow and pressure presses the septum primum (SP) against the walls of the septum secundum (SS), covering the foramen ovale and resulting in functional closure of the foramen ovale. This closure is usually followed by anatomical closure of the foramen ovale due to fusion of the septum primum (SP) to the septum secundum (SS).

[003] Where anatomical closure of the foramen ovale does not occur, a patent foramen ovale (PFO) is created. A patent foramen ovale is a persistent, usually flap-like opening between the atrial septum primum (SP)

and septum secundum (SS) of a heart. A patent foramen ovale results when either partial or no fusion of the septum primum (SP) to the septum secundum (SS) occurs. In the case of partial fusion or no fusion, a persistent passageway (PFO track) exists between the septum primum (SP) and septum secundum (SS). This opening or passageway is typically parallel to the plane of the SP, and has a mouth which is generally oval in shape. Fig. 2 shows the opening of the PFO track viewed from an end of the track. Normally the opening is relatively tall, but quite narrow. The opening may be held closed due to the mean pressure in the LA being typically higher than in the RA. In this manner, the SP acts like a one-way valve, preventing fluid communication between the right and left atria through the PFO track. However, at times, the pressure may temporarily be higher in the RA, causing the PFO track to open up and allow some fluid to pass from the RA to the LA, as indicated in Fig. 3. Although the PFO track is often held closed, the endothelialized surfaces of the tissues forming the PFO track prevent the tissue from healing together and permanently closing the PFO track. As can be seen in Fig. 4, (a view from line "C-C" of Fig. 1), the SP is firmly attached to the SS around most of the perimeter of the Fossa Ovalis, but has an opening along one side. The SP is often connected, as shown, by two or more extensions of tissue along the sides of the PFO track.

[004] Studies have shown that a relatively large percentage of adults have a patent foramen ovale (PFO). It is believed that embolism via a PFO may be a cause of a significant number of ischemic strokes, particularly in relatively young patients. It has been estimated that in 50% of cryptogenic

strokes, a PFO is present. Blood clots which form in the venous circulation (e.g., the legs) can embolize, and may enter the arterial circulation via the PFO, subsequently entering the cerebral circulation, resulting in an embolic stroke. Blood clots may also form in the vicinity of the PFO, and embolize into the arterial circulation and into the cerebral circulation. Patients suffering a cryptogenic stroke or a transient ischemic attack (TIA) in the presence of a PFO often are considered for medical therapy to reduce the risk of a recurrent embolic event.

[005] Pharmacological therapy often includes oral anticoagulants or antiplatelet agents. These therapies may lead to certain side effects, including hemorrhage. If pharmacologic therapy is unsuitable, open heart surgery may be employed to close a PFO with stitches, for example. Like other open surgical treatments, this surgery is highly invasive, risky, requires general anesthesia, and may result in lengthy recuperation.

[006] Nonsurgical closure of PFOs is possible with umbrella-like devices developed for percutaneous closure of atrial septal defects (ASD) (a condition where there is not a well-developed septum primum (SP)). Many of these conventional devices used for ASDs, however, are technically complex, bulky, and difficult to deploy in a precise location. In addition, such devices may be difficult or impossible to retrieve and/or reposition should initial positioning not be satisfactory. Moreover, these devices are specially designed for ASDs and therefore may not be suitable to close and seal a PFO, particularly because the septum primum (SP) overlaps the septum secundum (SS).

SUMMARY OF THE INVENTION

[007] In accordance with the invention, methods and devices for closing a passageway in a body, and more specifically closing a patent foramen ovale (PFO), are provided.

[008] According to one aspect of the invention, a method of sealing a passageway in a heart is provided. The method includes advancing an abrasion device into the passageway to be sealed, abrading at least a portion of the tissue surfaces forming the passageway, withdrawing the abrasion device from the passageway, and forcing abraded portions of the tissue surfaces of the passageway against one another for a period of time.

[009] According to another aspect of the invention, a device for sealing a passageway in a human body is provided. The device comprises a catheter having an distal portion, and at least one suture lumen, the at least one suture lumen containing a suture having an anchor at an end of the suture.

[010] According to yet another aspect of the invention, an assembly for sealing a passageway in a human body is provided. The assembly includes a delivery catheter, a suture connected to a barbed anchor, and a support tube configured to surround and support the suture.

[011] According to a further aspect of the invention, a method of sealing a passageway in a heart is provided. The method comprises advancing a hollow tubular structure into the passageway to be sealed, engaging the walls of the passageway with the hollow tubular structure, and flattening the hollow tubular structure.

[012] According to another aspect of the invention, a method of sealing a passageway in a heart includes advancing a catheter into the passageway, applying adhesive to the walls of the passageway, withdrawing the catheter from the passageway, and forcing portions of the walls of the passageway against one another for a period of time sufficient to allow the adhesive to at least partially cure.

[013] According to yet another aspect of the invention, a method of sealing a passageway in a heart is provided. The method comprises advancing a delivery device having an expandable end into the passageway, wherein the delivery device includes at least two suture lumens, each suture lumen having an open end positioned in the passageway when the delivery device is advanced into the passageway, expanding the expandable end, advancing a suture-anchor assembly out of the end of each suture lumen, penetrating the tissue forming the passageway with an anchor of each suture-anchor assembly, and pulling the passageway closed with the anchored sutures.

[014] According to another aspect of the invention, a method of sealing a passageway between a septum primum and a septum secundum in a heart is provided. The method includes advancing a delivery catheter into the right atrium, advancing an anchor and suture assembly out of the deliver catheter, and passing the anchor and suture assembly through the septum secundum and through the septum primum.

[015] Additional advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description,

or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

[016] The foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[017] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

[018] Fig. 1 is a short-axis view of the heart at the level of the right atrium (RA) and left atrium (LA), in a plane generally parallel to the atrio-ventricular groove, and at the level of the aortic valve, showing a PFO track.

[019] Fig. 2 is a cross-sectional view of the PFO track of Fig. 1 taken along line B-B, the PFO in a "closed" configuration.

[020] Fig. 3 is a cross-sectional view of the PFO track of Fig. 2 in an "open" configuration.

[021] Fig. 4 is cross-sectional view of the PFO track of Fig. 1 taken along line C-C.

[022] Fig. 5 is a perspective view of an abrasion device, according to an aspect of the present invention.

[023] Fig. 6 is a perspective view of the abrasion device of Fig. 5 positioned within a PFO track, according to an aspect of the present invention.

[024] Fig. 7 is a cross-sectional view of the PFO track of Fig. 6, after the abrasion device has been applied, with right atrial pressure reduced to permit closure of the PFO track, according to an aspect of the present invention.

[025] Figs. 8 and 9 are cross-sectional views of a catheter being used to close a PFO track, according to an aspect of the present invention.

[026] Fig. 10 is a perspective view of an embodiment of a self-flattening closure device in an open configuration according to one aspect of the present invention.

[027] Fig. 11 is a perspective view of the self-flattening closure device of Fig. 10 in a closed configuration.

[028] Figs. 12-14 are cross-sectional views of the self-flattening closure device of Figs. 10 and 11 with a delivery catheter and being deployed within a PFO track, according to an aspect of the present invention.

[029] Fig. 15 is a top view of an embodiment of a self-flattening closure device according to one aspect of the present invention.

[030] Fig. 16 is an end view of the self-flattening closure device of Fig. 15.

[031] Fig. 17 is a side view of the self-flattening closure device of Fig. 15.

[032] Fig. 18 is an end view of the self-flattening closure device of Fig. 15 in a partially flattened condition.

[033] Fig. 19 is an end view of the self-flattening closure device of Fig. 15 in a flattened configuration.

[034] Fig. 20 is an end view of the self-flattening closure device of Fig. 15 in an alternative flattened configuration.

[035] Fig. 21 is an enlarged perspective view of a strut of the self-flattening closure device of Fig. 15.

[036] Fig. 22 is a side view of the self-flattening closure device of Fig. 15 on a delivery catheter and connected to an adhesive lumen, according to an aspect of the present invention.

[037] Figs. 23-25 are cross-sectional views of the self-flattening closure device of Fig. 15, with the delivery catheter of Fig. 22, being deployed within a PFO track, according to an aspect of the present invention.

[038] Fig. 26 is a side view of a porous balloon catheter according to one aspect of the present invention.

[039] Fig. 27 is a cross-sectional view of the porous balloon catheter of Fig. 26 in an inflated condition.

[040] Fig. 28 is a cross-sectional view of the porous balloon catheter of Fig. 26 in a deflated condition.

[041] Figs. 29-31 are cross-sectional views of the porous balloon catheter of Fig. 26 being deployed within a PFO track, according to an aspect of the present invention.

[042] Fig. 32 is a longitudinal cross-sectional view of a portion of the porous balloon catheter of Fig. 26 filling and sealing the PFO track after deployment, according to an aspect of the present invention.

[043] Fig. 33A is a cross-sectional view of an alternative embodiment of a porous balloon in an inflated condition according to another aspect of the invention.

[044] Fig. 33B is a longitudinal cross-sectional view of the porous balloon of Fig. 33A connected to a catheter.

[045] Fig. 34 is a side view of a porous balloon catheter according to one aspect of the present invention.

[046] Fig. 35 is a first longitudinal cross-sectional view of the balloon of Fig. 34.

[047] Fig. 36 is a second longitudinal cross-sectional view of the balloon of Fig. 34 taken from an opposite side than Fig. 35.

[048] Fig. 37 is a cross-sectional view of the porous balloon of Fig. 34 in a deflated condition.

[049] Fig. 38 is a cross-sectional top view of the porous balloon of Fig. 34 in the deflated condition and taken along line A-A of Fig. 37.

[050] Fig. 39 is a cross-sectional view of a PFO closure device according to another aspect of the present invention.

[051] Figs. 40-42 are cross-sectional views of the PFO closure device of Fig. 39 in use to close a PFO track, according to an aspect of the present invention.

[052] Fig. 43 is a cross-sectional view of an alternative PFO closure device disposed within the right atrium, according to an aspect of the present invention.

[053] Fig. 44 is a cross-sectional view of an anchor and suture used with the PFO device of Fig. 43, according to an aspect of the present invention.

[054] Fig. 45 is a cross-sectional view of the anchor and suture of Fig. 44 after they have been deployed to close the PFO track, according to an aspect of the present invention.

DESCRIPTION OF THE EMBODIMENTS

[055] Reference will now be made in detail to embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[056] The various figures show embodiments of patent foramen ovale (PFO) closure devices and methods of using the devices to close a PFO. The devices and related methods are described herein in connection with use in sealing a PFO. These devices, however, also are suitable for closing other openings or passageways, including other such openings in the heart, for example atrial septal defects, ventricular septal defects, and patent ductus arterioses, and openings or passageways in other portions of a body such as an arteriovenous fistula. The invention therefore is not limited to use of the inventive closure devices to close PFOs.

[057] According to one aspect of the present invention, an abrasion device is provided. As embodied herein and shown in Fig. 5, an abrasion device 10 is provided for use in a method of closing a PFO track (referenced as PFO in the Figs.). The abrasion device 10 preferably includes an inflatable

balloon 12 having a plurality of abrasive elements 14 attached to an outer surface of the balloon 12. The abrasive elements 14 protrude beyond the outer surface of the balloon 12 and may form a surface similar to that of sandpaper. The abrasive elements 14 may be formed by abrasive material, for example microbeads, attached to the outer surface of the balloon 12 with an adhesive. Alternatively, the abrasive elements may be formed by any other suitable means. The adhesive should be strong enough to ensure that the abrasive material cannot come loose during contact with structures within the body, and should be flexible enough such that it does not inhibit the ability of the balloon to be inflated and deflated. An example of a preferred adhesive is a flexible adhesive such as polyurethane or epoxy.

[058] Alternatively, the abrasive elements may be formed by a plurality of small protuberances molded on the outside of the balloon, such that the outer surface of the balloon 12 has an abrasive quality once it is inflated. The abrasion device 10 need not utilize a balloon 12, but could be fabricated of an expandable material having an abrasive quality or a non-expandable tube-like element with an abrasive quality.

[059] The abrasion device 10 is attached to a catheter 16 (Fig. 6), which contains a lumen (not shown) for inflating and deflating the balloon 12. The abrasion device 10 is passed from an access site, preferably in the femoral vein, into the PFO track. The abrasion device 10 may be enclosed within a distal end of the catheter during passage to the PFO track so as to prevent damage to internal structures of the patient. Once positioned near the PFO track, the abrasion device 10 may be moved distally relative to the

end of the catheter by any suitable means known in the art. The abrasion device 10 is then inflated to place the abrasive elements 14 in contact with the tissue defining the PFO track, as shown in Fig. 6. Portions of the SP and SS which define the PFO track are then abraded with the abrasion device 10, for example, by rotating the abrasion device 10 within the PFO track or a linear back and forth motion of device 10 in the PFO track. Abrading the tissue surfaces of the PFO track denudes the endothelium on these tissue surfaces, setting up a healing response in the tissue and tending to cause the PFO track to heal closed over time.

[060] Since the patients are typically heparinized during endovascular procedures, and heparinization may inhibit the adhesion of the tissues to one another, it may be desirable to counter the effect of the heparin with protamine, bringing the patient back to a more normal coagulation state. However, if the heparin is countered, it is desired to have any remaining devices such as the balloon catheter in the inferior vena cava (IVC) to be coated with an appropriate anti-thrombotic coating such as heparin.

[061] In addition to an adverse heparin effect, other problems may prevent adherence between the septum primum (SP) and septum secundum (SS). Various methods are provided herein to enhance or ensure adherence between the abraded tissues. For example, during each heart beat, the RA pressure may be temporarily higher than the LA, potentially preventing the denuded tissue surfaces of the PFO track from adhering to one another long enough to promote long term healing of the surfaces in an apposed and closed condition. Therefore, a more active closure of the PFO track coupled

with the abrading step is preferred, at least for a period of several minutes, to assure long-term closure of the PFO track.

[062] One method of causing a more active temporary closure of the PFO track is illustrated in Fig. 7. After the tissue abrasion step is performed, the abrasion device 10 is removed. Then the venous return to the RA is temporarily reduced. One way to reduce the venous return is to temporarily occlude the inferior vena cava (IVC). This may be performed by positioning an inflatable balloon in the IVC for a period of several minutes to several hours. The reduction of venous return will reduce the pressure in the RA sufficiently such that the LA pressure will be sufficiently greater than the RA pressure, and the greater pressure in the LA will forcibly push the SP against the SS, closing the PFO track. While held against one another, the denuded tissue surfaces of the SS and SP will quickly pass through the initial stages of the healing response and adhere to one another more aggressively than they would under more normal RA pressures.

[063] An alternative active temporary closure method is illustrated in Figs. 8 and 9. In this method, a hollow catheter 16, such as a guiding catheter, is introduced and positioned with its distal end 16a in contact with the septum primum SP, at a location near the PFO track, as shown in Fig. 8. Once in position, a vacuum is created within the lumen of the catheter 16. The vacuum sucks or pulls the tissue of the septum primum SP into the end of the catheter 16, anchoring the catheter 16 to the septum primum SP. The vacuum can be created by any suitable means, such as with the use of a syringe connected in fluid communication with the lumen of the catheter or via

aspiration. Once the catheter 16 is anchored to the septum primum SP, the PFO track is temporarily closed by pulling or otherwise manipulating the catheter 16, as shown in Fig. 9, to pull the septum primum SP into apposition with the septum secundum SS.

[064] After a period of several minutes to several hours has passed as one of the above methods is employed, the PFO track will be reliably closed enough to assure the long term healing of the PFO track in a closed condition. At this point, any indwelling devices can be removed from the patient. One advantage of this PFO closure technique is that no foreign body remains in the patient, eliminating issues of foreign body reaction, thrombosis, or fatigue failure.

[065] These techniques of abrading the tissue surfaces of the PFO track and temporarily actively closing the abraded PFO track, as described above in conjunction with Figs. 6-9, may be individually combined with additional closure devices and methods described below.

[066] According to another aspect of the present invention, a PFO closure device is provided. As embodied herein and shown generically in Figs. 10 and 11, the PFO closure device comprises a tubular self-flattening closure (SFC) device 50. The SFC device 50 is configured to be positioned and left inside the PFO track. The SFC device 50 may be fabricated of a sheet or tube, and may comprise polymeric or preferably metallic materials, for example, a preferred material is an alloy of nickel-titanium. Such an alloy can have either shape-memory characteristics or super-elastic characteristics when formed and heat treated at particular temperatures, as is known in the

art. Preferably, the SFC device 50 is formed under such conditions to create a device 50 having a parent shape. The device is preferably formed to have a flattened parent configuration, i.e., a configuration which the device will assume when not under other forces, and above its martensite-to-austinite transition temperature. This is accomplished by forming and heat treating the device 50 in a flattened configuration. Then, when the device 50 is deformed to a non-flattened configuration during the delivery steps, it will return to a flattened configuration once the deforming forces are removed.

[067] The device thus has a first configuration during deployment within the PFO track that is tubular, for example circular, as shown in Fig. 10. The SFC device 50 may be positioned on a balloon catheter, which when inflated, the balloon holds the SFC device 50 in this configuration. When the balloon is deflated, the SFC device 50 returns to a second configuration, the parent shape resembling a flattened tube, as shown in Fig. 11. Within the PFO track, the flattened configuration is oriented such that it tautly maintains a width and a reduced thickness of the PFO track, preventing the PFO track from opening during periods of transient elevated RA pressures. Additionally, the SFC device serves to physically plug any remaining opening of the PFO track as shown in Figs. 12-14.

[068] Delivery and deployment of generic SFC device 50 is illustrated in Figs. 12-14. Fig. 12 shows an end view of the PFO track with the SFC device 50 in a pre-depolyed condition. The SFC device 50 is wrapped around the uninflated balloon 72 of a balloon catheter 70. The balloon catheter 70 with the SFC device 50 is introduced within the venous system, typically at an

access site in the femoral vein, and positioned within the PFO track, as shown. The balloon 72 is inflated to allow the SFC device 50 to make contact with the PFO track, as indicated in Fig. 13. When the balloon 72 is deflated and the catheter 70 is removed from the PFO track, the SFC device 50 takes on a flattened configuration, as shown in Fig. 14.

[069] A preferred embodiment of an SFC device 150 is shown in Figs. 15-20. Fig. 15 is a top view of SFC device 150. Fig. 16 is an end view of SFC device 150, and Fig. 17 is a side view of SFC device 150. SFC device 150 is formed from a metallic tube. Like a vascular stent, portions of the wall of the tube are removed by laser cutting, etching or other process to provide a structure having spaced supports.

[070] As shown in Fig. 15, the SFC device 150 includes a plurality of circumferential struts 152. The struts 152 comprise slightly less than half the circumference of the top and bottom sides of the SFC device 150. Along SFC device 150, are longitudinal strips 154. Preferably, two strips 54 are formed, spaced 180 degrees from one another, where corners of the device 150 are formed when the device is in the flattened configuration. As shown in Fig. 17, the upper and lower struts 152 may be longitudinally offset from each other. Such a configuration permits the SFC device 150 to be shape-set to a flattened configuration such that the upper and lower struts 152 don't interfere with each other once the device takes on its flattened configuration. That is, when the device 150 collapses from a tubular configuration to a flattened configuration, the struts 152 from a top half of the tube fit between the struts 152 of the bottom half of the tube. The offset further allows the SFC device

150 to be formed in a parent shape such that the struts 152 are actually pushed through or over-set relative to each other (Fig. 20). When such a parent shape is deformed in the SFC device 150 due to other forces, as shown in Fig. 18, the device 150 is urged toward a flattened configuration (Fig. 19) with the struts 152 of the top half of the device being alternately positioned between struts 152 of the bottom half of the device when the other forces are removed. The top and bottom struts 152 can then actually move past each other in the absence of any other forces (Fig. 20), i.e., the top struts 152 pass through the spaces between the bottom struts 152 until the parent configuration is achieved. By forming the SFC device 150 with such an over-set parent shape, the SFC device 150 more aggressively takes on a flattened configuration when positioned within the PFO track, particularly when further tissue attaching mechanisms are employed, as described below.

[071] According to another aspect of the invention, the SFC device 150 may include an adhesive tissue attaching mechanism. As embodied herein and shown in Fig. 21, at least some of the struts 152 include a hollow lumen 156 and may be placed in fluid communication with an adhesive delivery lumen 160 (see Fig. 22). The lumens 156 of struts 152 are in fluid communication with a lumen (not shown) which extends within one of the longitudinal struts 154 of the SFC device 150 and is in fluid communication with adhesive delivery lumen 160. Struts 152 may also include a plurality of outwardly directed holes 158, which provide for delivery of an adhesive from the struts 152 to the tissue surfaces defining the PFO track. A preferred adhesive is one that cures upon exposure to moisture, such as a

cyanoacrylate. Other suitable adhesives, such as, for example, fibrin glue, a two-part epoxy, or polyurethane, may be used.

[072] In use, the SFC device 150 is positioned on a balloon 172 of a balloon catheter 170. A detachable tube defines an adhesive delivery lumen 160, and provides for adhesive to be delivered to the lumens of struts 152, 154. The delivery lumen 160 is connected to a source of adhesive at a proximal end of the catheter 170, by any suitable means known in the art. The SFC device 150 on the balloon catheter 170, carrying SFC device 150, is passed from an access site, preferably in the femoral vein, into the PFO track (Fig. 23). When the balloon 172 is expanded, as in Fig. 24, a suitable adhesive 162 is injected through lumen 160, through the lumen in longitudinal strut 154, into lumens 156 of hollow struts 152 until it emerges from the holes 158 and contacts the walls of the PFO track. The detachable tube forming lumen 160 is then removed from the SFC device 50 by a suitable detachment mechanism, for example, by a breakaway section that breaks upon torsion. After the adhesive cures, the SFC device 150 is firmly attached to the tissue. Once sufficient curing has taken place to ensure that the SFC device 150 will remain attached to the walls of the PFO track, the balloon 172 is deflated and the catheter 170 is removed, allowing the SFC device 150 to flatten (Fig. 25). Since the parent shape is preferably an over-set flattened shape as described above, the SFC device 150 will aggressively form a flattened shape, bringing the walls of the PFO track, which are adhered to the SFC device 150, in close apposition, and thus closing the PFO track (Fig. 25). Over time, additional scar tissue will form within and around the SFC device 150, creating a long-

term robust seal of the PFO track. The healing response following implantation of the various embodiments of the SFC device 150 may be further enhanced by prior abrading of the PFO track, as described above in connection with the device of Fig. 5.

[073] Alternatively, it may be possible to deflate and remove the balloon 172 and catheter 170 prior to curing of the adhesive. In such a case, the SFC device 150 will flatten prior to the walls of the PFO track adhering to the device 150. Therefore, it would be desirable to use one of the methods described with respect to Figs. 7-9 to press the walls of the PFO track into the SFC device 150 while the adhesive cures.

[074] According to another aspect of the present invention, an alternative PFO closure device is provided. As embodied herein and shown in Figs. 26-32, the PFO closure device may comprise a porous balloon catheter. Fig. 26 shows the distal end of a balloon catheter having a porous balloon, herein after referred to as a porous balloon catheter (PBC) 180. PBC 180 includes an inflatable balloon 182 having a plurality of small holes 184 that perforate the balloon 182. Fig. 27 shows a cross-section of the porous balloon 182 in an inflated state and Fig. 28 shows a cross-section of the porous balloon 182 in a deflated state. A detachable tube 186 is connected to a proximal end 188 of the balloon 182.

[075] Use of the PBC 180 in closing a PFO track is illustrated in Figs. 29-32. The PBC 180 is introduced into the venous circulation through standard techniques, and the balloon 182 is positioned within the PFO track, as shown in Fig. 29. The balloon 182 is then inflated with a fluid that exhibits

adhesive-like qualities once cured. Initially, the balloon 182 inflates, expanding the PFO track and making circumferential contact with the tissue defining the PFO track, as shown in Fig. 30. Further pressurization of the balloon 182 then causes some of the liquid adhesive to squeeze out of the pores and form an adhesive film 190 between the walls of the PFO and the outer surface of the balloon 182 (also shown in Fig. 30). Once the adhesive leaves the balloon 182, it cures upon contact with the moist tissue defining the PFO track. As the cure of the adhesive progresses from the walls of the PFO track towards the liquid adhesive inside the balloon 182, the balloon 182 is deflated, bringing the walls of the PFO track, which are now adhered to the balloon 182 via the adhesive film 190, along with it. Once the balloon 182 is deflated, a thin film of adhesive remaining on the inside of the balloon 182 is allowed to cure, and the PFO track is closed (Fig. 31), leaving balloon 182 and adhesive 190 therein. The detachable tube 186 is then removed by a suitable detachment mechanism, such as that described above in connection with the removable tube of the SFC device 150. The bonded-in balloon 182 is left behind in the PFO track (Fig. 32).

[076] The bonded-in balloon 182 will heal in place, resulting in a robust long-term closure of the PFO track. This closure technique results in a minimum amount of foreign body with virtually no contact with blood in either the RA or LA, and as with all devices within the present application, little chance or consequence of mechanical fatigue failure. Also, the PBC 180 and method could be combined with a prior abrading step, as previously described in connection with the device of Fig. 5.

[077] Preferably, the balloon 182 is sized to have a diameter of a size relatively similar to the diameter of the PFO track once expanded, i.e., the perimeter of the balloon is approximately equal to the perimeter of the PFO track, and a length equal to or somewhat shorter than the length of the PFO track. Suitable biocompatible polymers for the porous balloon are preferably polyethylene, expanded polytetrafluoroethylene, PET, Nylon, silicone, polyurethane, or Pebax. The balloon 182 is preferably inflatable by a fluid adhesive. A preferred adhesive is one which cures upon exposure to moisture, such as a cyanoacrylate. The adhesive may be provided to balloon 182 by, for example, a lumen in tube 186 connected to a source of adhesive.

[078] Alternatively, the balloon 182 of the PBC 180 need not be left in the PFO track. In such an embodiment, the tube 186 need not be detachable. In use, the porous balloon 182 is positioned in the PFO track and inflated as shown in Figs. 29 and 30. However, the balloon 182 is deflated and removed prior to curing of the adhesive such that the balloon surface does not adhere to the wall of the PFO track. Thus, after removal of balloon 182, adhesive covers at least some of the walls of the PFO track. In this embodiment, it is preferred that the adhesive not cure instantly, but rather take at least a few minutes, providing sufficient time to remove the balloon 182 and catheter 180 without causing adhesion between the balloon 182 and the walls of the PFO track. Suitable adhesives for this embodiment are similar to those discussed above, but it is important to select an adhesive with a long enough cure time to minimize curing while the balloon 182 is still present in the PFO track.

[079] In addition, in this embodiment where balloon 182 is not left in the PFO track, the PFO track may be forced closed utilizing any of the steps described above in connection with Figs. 7-9. Once the adhesive is sufficiently cured, the venous return can be brought back to normal, if the method shown in Fig. 7 is employed, or the catheter with vacuum can be removed if the method employed in Figs. 8 and 9 is employed, resulting in a robust closure of the PFO track. In this embodiment, only a relatively small amount of a biocompatible adhesive is left behind in the PFO track. And again, for this embodiment, a prior denudation of the walls of the PFO track may further enhance the robustness of the PFO track closure.

[080] According to another aspect of the present invention, an alternative embodiment of a PFO closure device is provided. As embodied herein and shown in Figs. 33A and 33B, the PFO closure device comprises a balloon catheter 280 having a porous balloon 282. Balloon catheter 280 includes a shaft 286 attached to a proximal end 288 of an inflatable balloon 282. The shaft 286 may or may not be detachable. The balloon 282 comprises two layers, an inner layer 283a, which is not porous, and an outer layer 283b, which is porous. The dual layer balloon 282 is connected to the catheter shaft 286, having a first lumen 286a in fluid communication with the interior of the inner layer 283a, and a second lumen 286b in fluid communication with a space 285 between the inner and outer layers 283a, 283b. The second lumen 286b is used for delivery of an adhesive, while the first lumen 286a is used for inflation and deflation of the dual layer balloon 282. Since the inner layer 283a is non-porous, inflation and deflation of this

dual layer balloon 282 can be performed completely independently of adhesive delivery.

[081] In use, balloon 282 is used in a manner similar to that described above with respect to Figs. 26-30. The balloon 282 is introduced to the PFO track, then inflated, and adhesive is delivered via the porous outer layer 283b to the walls of the PFO track. The balloon 282 is then deflated and removed, optionally followed by forced closure of the PFO track, as previously described in connection with Figs. 7-9. Alternatively, the balloon 282 might be detached from the catheter shaft and left implanted in the PFO track as previously described with respect to Figs. 26-32.

[082] According to another aspect of the present invention, a PFO closure device is provided. As embodied herein and shown in Figs. 34-38, a dual layer porous balloon, similar to the balloon shown in Figs. 33A and 33B, is provided. In this embodiment, the balloon 382 is connected to a detachable shaft 386. The interior surface 381 of the balloon 382 also includes an adherence mechanism 390. Adherence mechanism 390 preferably includes strips of a mechanical interlocking structure, such as Velcro. Strips of Velcro are preferably arranged in a helical fashion on the interior surface 381 of the balloon 382. The strips are positioned such that rows of "hooks" H alternate with rows of "loops" L. The adherence mechanism 390 serves to maintain the balloon 382 in a deflated condition upon removal of inflation medium from the balloon 382.

[083] Fig. 35 shows the alternating strips of hooks (H) and loops (L) on the inner surface 381 of one half of the balloon 382, and Fig. 36 shows the

alternating strips on the inner surface 381 of the opposite half of the balloon 382. When the balloon 382 is deflated, the inner surfaces 381 of the two balloon halves come together, forcing the Velcro strips to make contact in at least a plurality of locations where they intersect (Figs. 37-38).

[084] In use, the porous balloon catheter is used in a similar manner as that described in connection with the steps shown in Figs. 26-33B. The balloon 382 is introduced to the PFO track, inflated at a sufficiently high pressure to disengage the Velcro strips of the adherence mechanism, and adhesive is delivered via the porous outer layer 383b to the walls of the PFO track. The balloon 382 is then deflated and the rows of Velcro on the interior 381 of the balloon 382 come into contact with one another, holding the balloon 382 in a flattened configuration. The catheter shaft 386 is detached from the balloon 382, and the balloon is left implanted in the PFO track as previously described with respect to Figs. 26-32.

[085] According to another aspect of the invention, an alternative embodiment of a PFO closure device is provided. As embodied herein and shown in Figs. 39-42, the PFO closure device includes a delivery device 400 carrying suture-anchor assemblies 401. Each suture-anchor assembly 401 includes a barbed anchor 402 connected to a suture tie 404. Suitable suture tie materials include those typically used in surgical closure of PFO tracks, such as degradable or non-degradable type commercially available suture material, monofilament or braided type commercially available suture material. The barbed anchors 402 and suture ties 404 are used to mechanically close the PFO track from within the lumen of the PFO track.

[086] The delivery device 400 contains a plurality of suture lumens 406, one for each suture-anchor assembly 401. Each suture lumen 406 terminates in an opening 408. As shown in Fig. 39, each suture lumen 406 is located on an opposite side of the delivery device 400, such that the suture lumens are spaced approximately 180 degrees apart from one another. An expandable head of the delivery device, for example a balloon 410, allows the suture lumen openings 408 to be displaced radially outward. This causes the PFO track to be dilated and stretched taut, which facilitates penetration of the anchors into the tissue surrounding the PFO track.

[087] In use, the delivery device 400 is positioned within the PFO track, in a non-deployed condition. The suture-anchor assemblies 401 are positioned within the suture lumens 406, with the anchors 402 also residing in the suture lumens 406. Once the suture lumen openings 408 are in a desired position within the PFO track, the expandable head 410 is deployed (i.e., the balloon 410 is inflated). Then the suture-anchor assemblies 401 are advanced until the anchors 402 emerge from the suture lumen openings 408 and penetrate into the tissue forming the PFO track. To assist in supporting suture anchor assemblies 401 during advancement and penetration, it may be useful to surround the suture ties 404 with a separate tubular support members (not shown), which are advanced with the suture anchor assemblies 401. Tubular support members are removed proximally after anchors 402 are deployed. This step in the procedure is illustrated in Figs. 39 and 40.

[088] Once the anchors are firmly engaged in the tissue, balloon 410 is deflated and the delivery device 400 is removed, leaving the sutures 404

extending outside the access site of the patient. While two sutures are shown, it is contemplated that any number of sutures, two or more, could be placed. The sutures 404 are tied into a knot 412 by any suitable method, as shown in Fig. 41, and the knot 412 is pushed towards the anchors 402 with the help of a knot pushing device (not shown). Once the knot 412 is tightened against the walls of the PFO track, the walls are brought into apposition, and the suture tails are cut, resulting in the configuration illustrated in Fig. 42. Cutting of the suture tails can be accomplished by any suitable endovascular cutting mechanism known in the art.

[089] While these suture and anchor assemblies 401 can be used as a sole mechanism for PFO closure, it is preferable to combine this device with a prior abrading of the walls of the PFO track as described previously. When combined as such, the PFO track will heal to a robustly closed condition.

[090] According to another aspect of the invention, another embodiment of a PFO closure device is provided. As embodied herein and shown in Figs. 43-45, a delivery catheter 500 is positioned within the RA such that the tip 500a is adjacent the SS, near the PFO track. A suture and anchor assembly 501 comprising a suture 504 with a barb-like anchor 502 is advanced through the SS, and through the SP, bridging the PFO track roughly perpendicular to the longitudinal aspect of the PFO track (Fig. 43). Suitable suture tie materials include those typically used in surgical closure of PFO tracks, such as degradable or non-degradable type commercially available suture material, monofilament or braided type commercially available suture material. Barb-like anchor 502 preferably includes tines 502a which are self-

expanding once they emerge from the tissue. Once the barb-like anchor 502 is passed through the SP, the barb opens up and acts as a strong securement for the suture. Although only one suture and anchor assembly 501 is illustrated in Figs. 43-45, more than one may be used as necessary to ensure sufficient closure of the PFO track.

[091] To help facilitate advancement of the suture and anchor assembly 501 across the SS and SP, it may be necessary to provide additional support to the relatively flexible suture 504. Fig. 44 shows a support tube 506 surrounding the suture. Support tube 506 preferably has high column support, but enough lateral flexibility to negotiate any curves within the delivery catheter 500. Suitable materials include metals and relatively rigid polymers. Preferred metals include Ni-Ti alloy and stainless steel. Preferred polymers include polyimide and PEEK. The support tube 506 helps advance the anchor 502 and suture 504 across the tissue, and is removed after the anchor is deployed across the SP.

[092] After the barb-like anchor 502 is deployed, a lock device 508, preferably a one-way device, such as, for example, a releasable fixation mechanism (disclosed in U.S. Patent Application No. 09/870,813, filed on June 1, 2001, and entitled "Closure Devices, Related Delivery Methods and Tools, and Related Methods of Use," the entire disclosure of which is incorporated herein by reference), is advanced along the suture 504, pulling the SP and SS together. The remaining suture length is then cut by suitable techniques. While this suture-based concept may be performed as a sole therapy it is preferable to combine this suture closure with a prior abrading of

the tissue forming the PFO track to facilitate a robust long-term closure of the PFO.

[093] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. The specification and examples are exemplary, with a true scope and spirit of the invention being indicated by the following claims.

WHAT IS CLAIMED IS:

1. A method of sealing a passageway in a heart, comprising:

advancing an abrasion device into the passageway to be sealed;

abrading at least a portion of the tissue surfaces forming the passageway;

withdrawing the abrasion device from the passageway; and

forcing abraded portions of the tissue surfaces of the passageway against one another for a period of time.

2. The method of claim 1, wherein the forcing abraded portions of the tissue surfaces together includes reducing venous return to the right atrium.

3. The method of claim 2, wherein reducing venous return to the right atrium includes occluding the inferior vena cava.

4. The method of claim 3, wherein occluding the inferior vena cava includes positioning an inflatable balloon in the inferior vena cava.

5. The method of claim 1, wherein the forcing abraded portions of the tissue surfaces together includes applying a vacuum to the septum primum.

6. The method of claim 5, wherein applying a vacuum includes anchoring a catheter to the septum primum via the vacuum.

7. The method of claim 6, wherein anchoring a catheter to the septum primum includes creating the vacuum with a syringe in fluid communication with a lumen of the catheter.

8. The method of claim 1, further comprising providing an adhesive to at least a portion of the tissue surfaces forming the passageway prior to forcing the abraded portions together.

9. The method of claim 9, wherein providing the adhesive includes advancing a closure device into the passageway subsequent to withdrawing the abrasion device.

10. The method of claim 9, further comprising supplying adhesive to the closure device.

11. The method of claim 9, wherein the closure device is self-flattening.

12. The method of claim 11, further comprising providing the closure device on a balloon catheter and expanding a balloon of the balloon catheter within the passageway to place the self-flattening closure device in an expanded configuration.

13. The method of claim 12, wherein supplying adhesive includes providing adhesive to hollow portions of the self-flattening closure device.

14. The method of claim 13, wherein supplying adhesive further includes passing the adhesive through holes in the self-flattening closure device to at least a portion of the tissue surfaces forming the passageway.

15. The method of claim 8, further comprising providing a catheter having a porous balloon.

16. The method of claim 15, wherein providing adhesive includes inflating the porous balloon with a liquid adhesive.

17. The method of claim 15, further comprising expanding an inner layer of the porous balloon within the passageway.

18. The method of claim 16, wherein providing adhesive includes filling an outer layer of the porous balloon with a liquid adhesive.

19. The method of claim 1, wherein the passageway is a patent foramen ovale.

20. A device for sealing a passageway in a human body, the device comprising:

a catheter having an distal portion; and

at least one suture lumen, the at least one suture lumen containing a suture having an anchor at an end of the suture.

21. The device of claim 20, further comprising two suture lumens, wherein each suture lumen contains a suture having an anchor at an end of the suture.

22. The device of claim 20, wherein the anchor has a sharp tip.

23. The device of claim 20, wherein the anchor includes a barbed end.

24. The device of claim 21, wherein each anchor includes a barbed end.

25. The device of claim 21, wherein one of the at least two suture lumens is positioned on a first side of the catheter and wherein the other of the at least two suture lumens is positioned on an opposite side of the catheter.

26. The device of claim 25, wherein the at least two suture lumens are spaced approximately 180 degrees apart.

27. The device of claim 20, wherein the at least one suture lumen has an open distal end.

28. The device of claim 21, wherein each of the two suture lumens has an open distal end.

29. The device of claim 20, wherein the expandable distal portion includes a balloon.

30. An assembly for sealing a passageway in a human body, comprising:

a delivery catheter;

a suture connected to a barbed anchor; and

a support tube configured to surround and support the suture.

31. The assembly of claim 30, further comprising a lock device.

32. The assembly of claim 31, wherein the lock device is configured to engage the suture.

33. The assembly of claim 32, wherein the lock device is configured to move in only one direction along the suture.

34. The assembly of claim 30, wherein the anchor includes sharp tips.

35. The assembly of claim 30, wherein the anchor includes barbed portions.

36. The assembly of claim 35, wherein the barbed portions are moveable between an expanded configuration and a collapsed configuration.

37. The assembly of claim 30, wherein the support tube is positioned within the catheter.

38. A method of sealing a passageway in a heart, comprising:

advancing a hollow tubular structure into the passageway to be sealed;

engaging the walls of the passageway with the hollow tubular structure; and

flattening the hollow tubular structure.

39. The method of claim 38, wherein engaging the walls includes expanding the hollow tubular structure.

40. The method of claim 39, wherein engaging the walls further includes supplying an adhesive from the hollow tubular structure to the walls of the passageway.

41. The method of claim 40, wherein expanding the hollow tubular structure includes inflating a balloon.

42. The method of claim 41, wherein inflating the balloon includes supplying a liquid adhesive to inflate the balloon.

43. The method of claim 42, wherein supplying adhesive from the hollow tubular structure includes continuing to supply the liquid adhesive to the balloon until adhesive passes through pores of the balloon to an outer surface of the balloon.

44. The method of claim 41, wherein inflating the balloon includes supplying an inner layer of the balloon with a fluid.

45. The method of claim 44, wherein supplying the adhesive includes supplying an outer layer of the balloon with a liquid adhesive.

46. The method of claim 45, wherein supplying the adhesive further includes continuing to supply the liquid adhesive to the outer layer of the balloon until adhesive passes through pores of the outer layer of the balloon to an outer surface of the balloon.

47. The method of claim 40, further comprising allowing the adhesive to at least partially cure prior to flattening the hollow tubular structure.

48. The method of claim 47, wherein flattening the hollow tubular structure pulls the walls of the passageway toward each other.

49. The method of claim 47, wherein flattening the hollow tubular structure includes deflating a balloon.

50. The method of claim 49, wherein deflating the balloon includes deflating the balloon of a delivery catheter, and further comprising the step of removing the delivery catheter.

51. The method of claim 50, wherein deflating the balloon further includes allowing the hollow tubular structure comprising a shape memory alloy to flatten.

52. The method of claim 40, further comprising leaving the flattened hollow tubular structure within the passageway.

53. The method of claim 38, further comprising abrading at least a portion of the walls of the passageway prior to advancing the hollow tubular structure into the passageway.

54. The method of claim 53, further comprising forcing abraded portions of the tissue surfaces of the passageway against one another subsequent to flattening the hollow tubular structure.

55. The method of claim 54, wherein the forcing abraded portions of the tissue surfaces together includes reducing venous return to the right atrium.

56. The method of claim 54, wherein the forcing abraded portions of the tissue surfaces together includes applying a vacuum to the septum primum.

57. The method of claim 52, further comprising abrading at least a portion of the walls of the passageway prior to advancing the hollow tubular structure into the passageway.

58. The method of claim 57, further comprising forcing abraded portions of the tissue surfaces of the passageway against one another subsequent to flattening the hollow tubular structure.

59. The method of claim 58, wherein the forcing abraded portions of the tissue surfaces together includes reducing venous return to the right atrium.

60. The method of claim 58, wherein the forcing abraded portions of the tissue surfaces together includes applying a vacuum to the septum primum.

61. The method of claim 40, further comprising removing the flattened hollow tubular structure from the passageway.

62. The method of claim 61, further comprising abrading at least a portion of the walls of the passageway prior to advancing the hollow tubular structure into the passageway.

63. The method of claim 62, further comprising forcing abraded portions of the tissue surfaces of the passageway against one another subsequent to flattening the hollow tubular structure.

64. The method of claim 63, wherein the forcing abraded portions of the tissue surfaces together includes reducing venous return to the right atrium.

65. The method of claim 63, wherein the forcing abraded portions of the tissue surfaces together includes applying a vacuum to the septum primum.

66. The method of claim 41, wherein inflating the balloon includes expanding the balloon of a delivery catheter to expand a self-flattening closure device comprising a shape memory alloy.

67. The method of claim 66, wherein supplying the adhesive includes supplying adhesive from a supply lumen to a lumen within a longitudinal strut of the self-flattening closure device.

68. The method of claim 67, wherein supplying the adhesive further includes supplying the adhesive from the lumen of the longitudinal strut to a plurality of lumens in circumferential struts of the self-flattening closure device.

69. The method of claim 68, wherein supplying the adhesive further includes passing adhesive from the lumens of the circumferential struts

through holes in the circumferential struts to an outer surface of the self-flattening closure device.

70. The method of claim 69, further comprising allowing the adhesive to at least partially cure prior to flattening the hollow tubular structure.

71. The method of claim 70, wherein flattening the hollow tubular structure pulls the walls of the passageway toward each other.

72. The method of claim 71, wherein flattening the hollow tubular structure includes allowing the self-flattening closure device to assume a flattened configuration.

73. The method of claim 72, further comprising leaving the self-flattening closure device in its flattened configuration within the passageway.

74. The method of claim 38, wherein the passage is a patent foramen ovale.

75. A method of sealing a passageway in a heart, comprising:

advancing a catheter into the passageway;

applying adhesive to the walls of the passageway;

withdrawing the catheter from the passageway; and

forcing portions of the walls of the passageway against one another for a period of time sufficient to allow the adhesive to at least partially cure.

76. The method of claim 75, wherein applying adhesive to the walls of the passageway includes expanding a porous balloon.

77. The method of claim 76, wherein expanding the porous balloon includes filling the balloon with a liquid adhesive until the adhesive passes through pores of the balloon to an outer surface of the balloon.

78. The method of claim 76, wherein expanding the balloon includes inflating an inner layer of the balloon.

79. The method of claim 78, wherein expanding the balloon further includes filling an outer layer of the balloon with a liquid adhesive until the adhesive passes through pores of the balloon to an outer surface of the balloon.

80. The method of claim 76, further comprising deflating the porous balloon prior to withdrawing the catheter.

81. The method of claim 75, further comprising abrading portions of the walls of the passageway prior to advancing the catheter into the passageway.

82. The method of claim 75, wherein forcing portions of the walls of the passageway together includes reducing venous return to the right atrium.

83. The method of claim 82, wherein reducing venous return to the right atrium includes occluding the inferior vena cava.

84. The method of claim 83, wherein occluding the inferior vena cava includes positioning an inflatable balloon in the inferior vena cava.

85. The method of claim 75, wherein forcing portions of the walls of the passageway together includes applying a vacuum to the septum primum.

86. The method of claim 85, wherein applying a vacuum includes anchoring a catheter to the septum primum via the vacuum.

87. The method of claim 86, wherein anchoring a catheter to the septum primum includes creating the vacuum with a syringe in fluid communication with a lumen of the catheter.

88. A method of sealing a passageway in a heart, comprising:

advancing a delivery device having an expandable end into the passageway, wherein the delivery device includes at least two suture lumens, each suture lumen having an open end positioned in the passageway when the delivery device is advanced into the passageway;

expanding the expandable end;

advancing a suture-anchor assembly out of the end of each suture lumen;

penetrating the tissue forming the passageway with an anchor of each suture-anchor assembly; and

pulling the passageway closed with the anchored sutures.

89. The method of claim 88, wherein pulling the passageway closed includes tying the sutures in a knot.

90. The method of claim 88, further comprising abrading portions of the tissue surfaces forming the passageway prior to advancing the delivery device.

91. The method of claim 88, wherein expanding the expandable end includes inflating a balloon.

92. A method of sealing a passageway between a septum primum and a septum secundum in a heart, comprising:

advancing a delivery catheter into the right atrium;

advancing an anchor and suture assembly out of the delivery catheter; and

passing the anchor and suture assembly through the septum secundum and through the septum primum.

93. The method of claim 92, wherein advancing the anchor and suture assembly includes advancing a support tube surrounding a suture of the anchor and suture assembly.

94. The method of claim 93, wherein passing the anchor and suture assembly through the septum secundum and through the septum primum includes passing the support tube surrounding the suture through the septum secundum and through the septum primum.

95. The method of claim 92, further comprising abrading the passageway prior to advancing the delivery catheter into the right atrium.

96. The method of claim 92, further comprising moving a locking device along a portion of the suture extending between the septum secundum and the delivery catheter.

97. The method of claim 96, wherein moving the locking device includes moving the locking device until the locking device is adjacent the septum secundum and the suture is taut.

98. The method of claim 97, further comprising cutting the suture between the locking device and the delivery catheter.

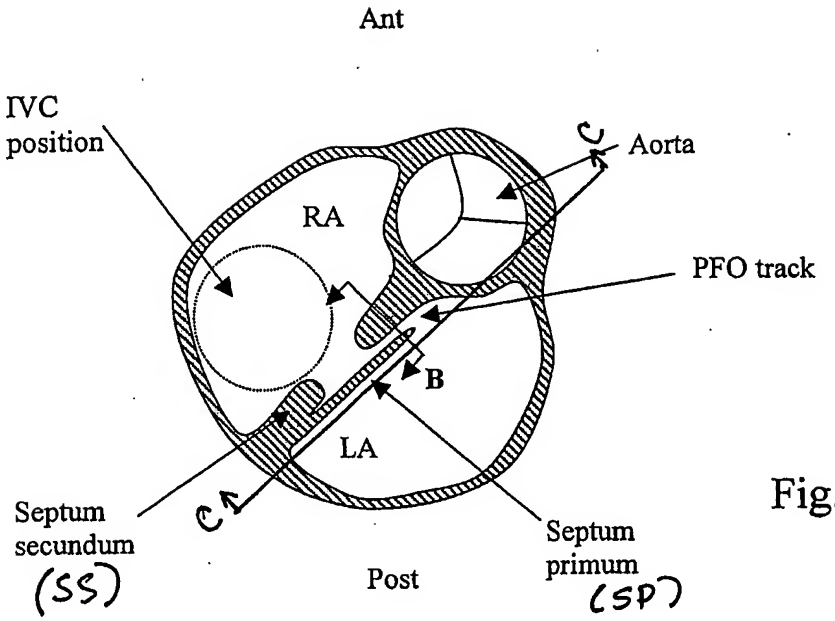

Fig. 1

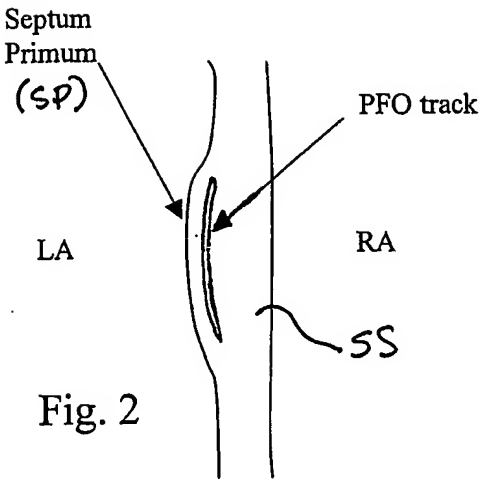

Fig. 2

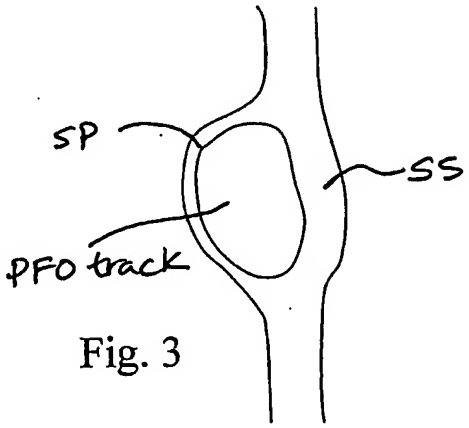

Fig. 3

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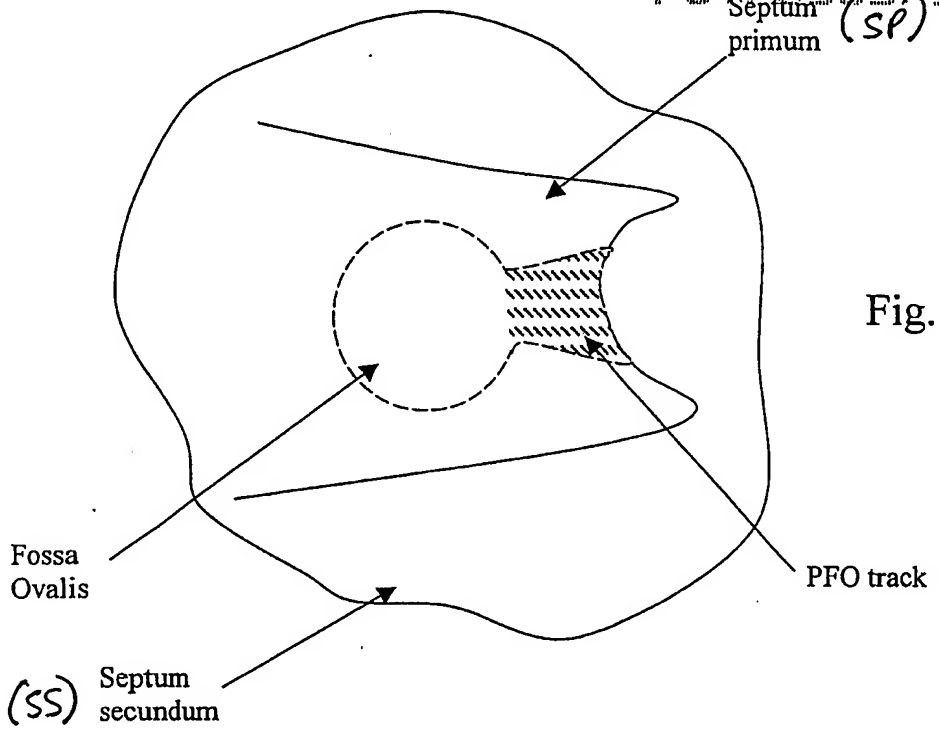

Fig. 4

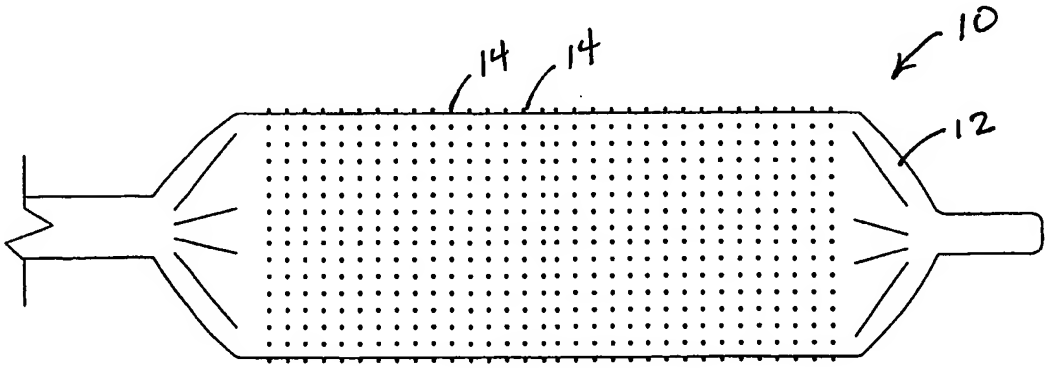

Fig. 5

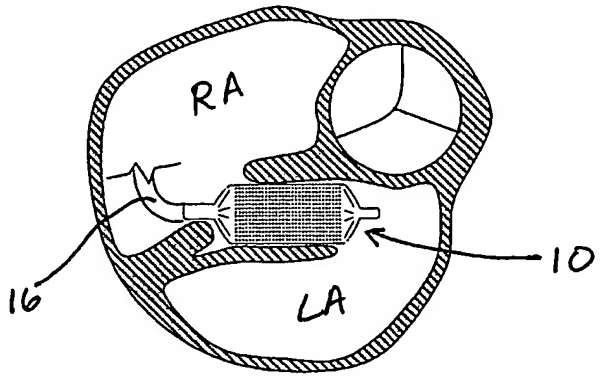

Fig. 6

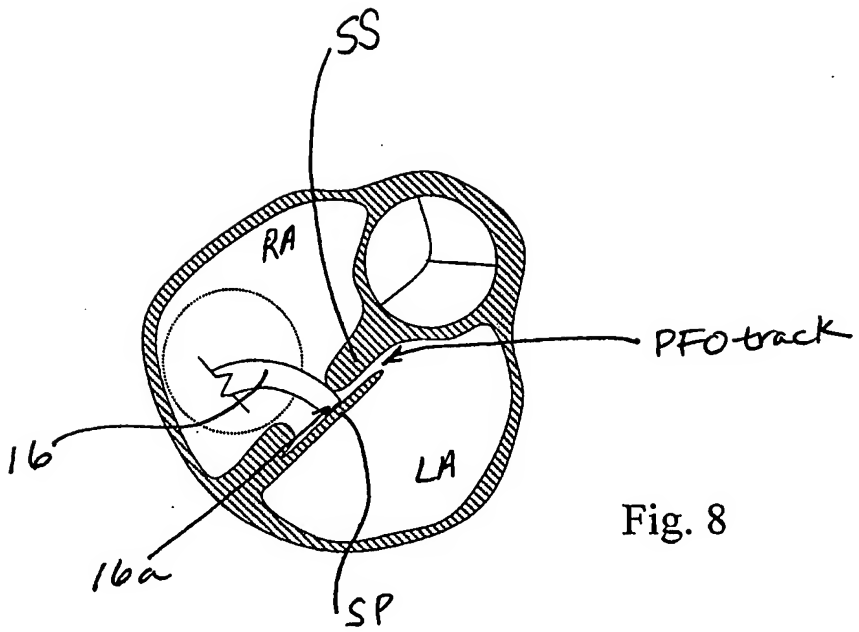

Fig. 8

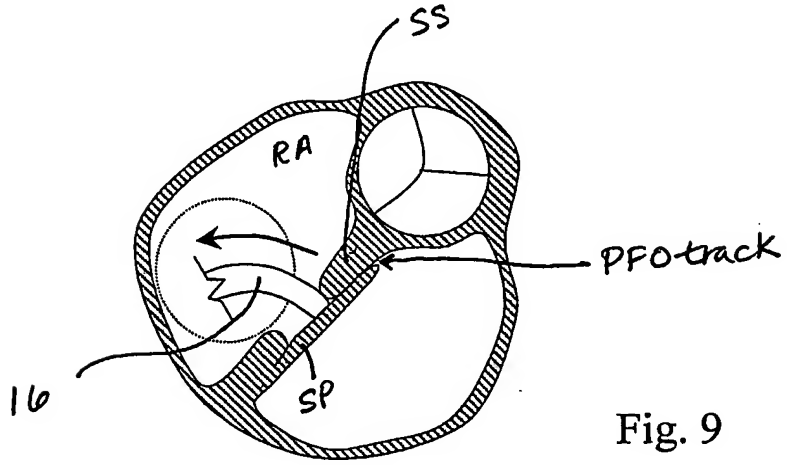

Fig. 9

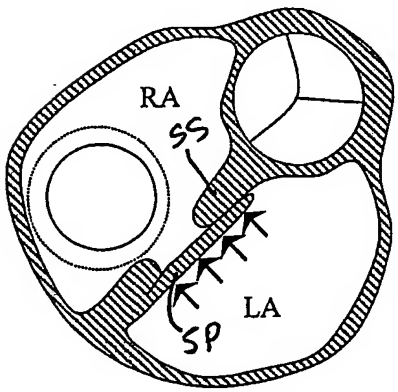

Fig. 7

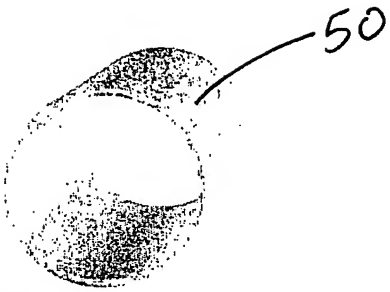

Fig. 10

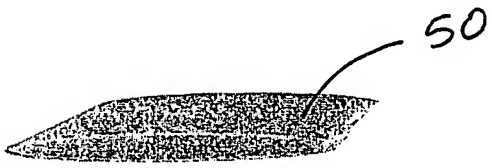

Fig. 11

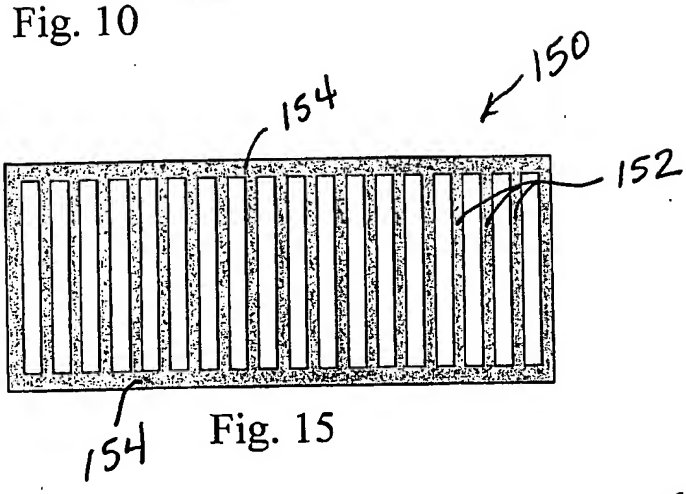

Fig. 15

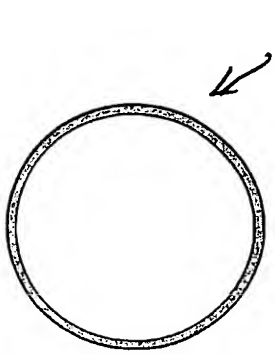

Fig. 16

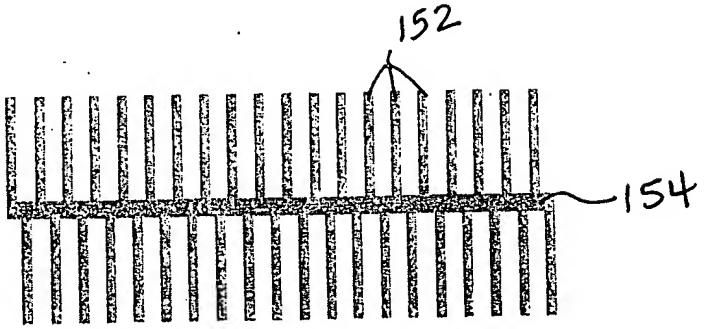

Fig. 17

Fig. 18

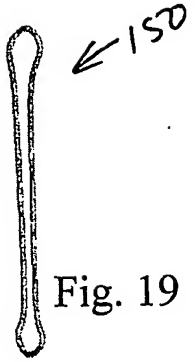

Fig. 19

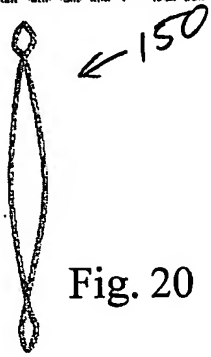

Fig. 20

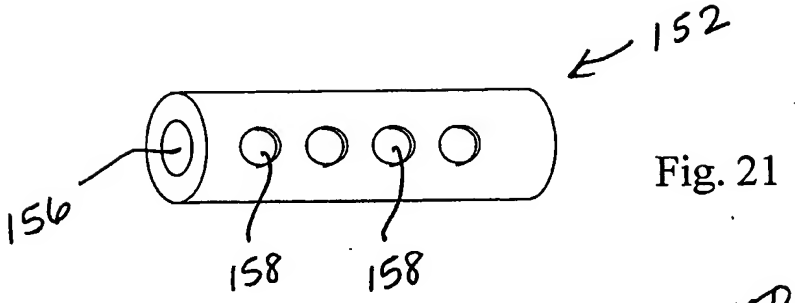

Fig. 21

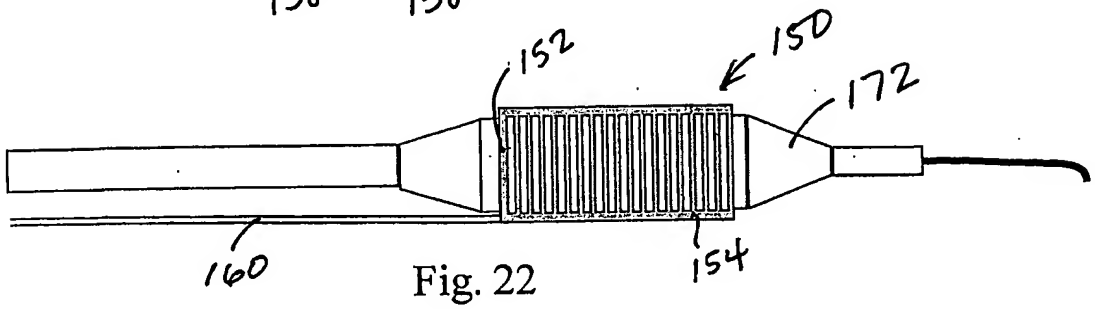

Fig. 22

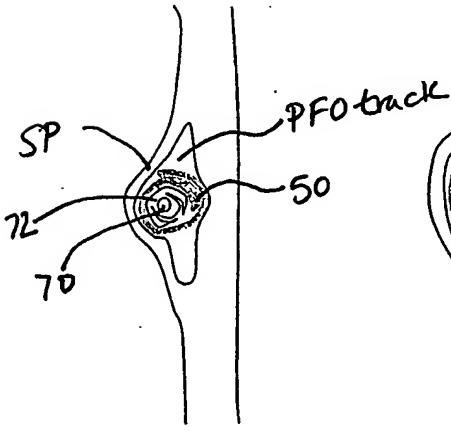

Fig. 12

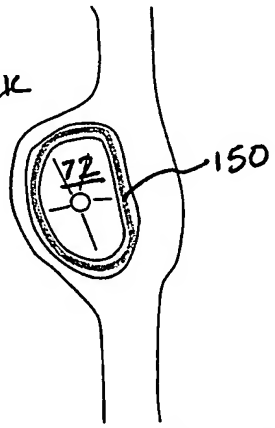

Fig. 13

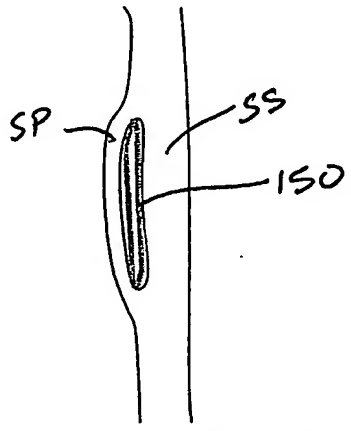

Fig. 14

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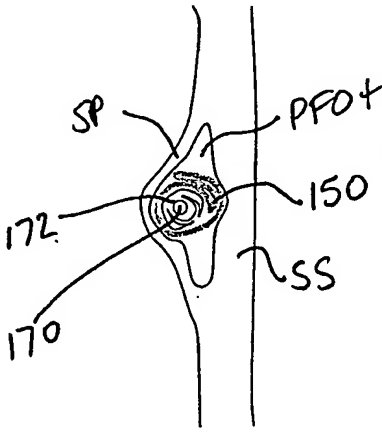

Fig. 23

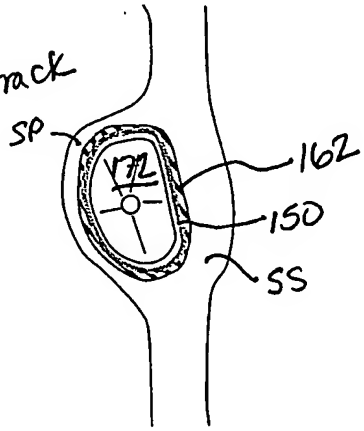

Fig. 24

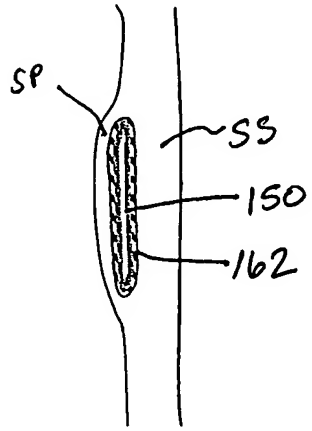

Fig. 25

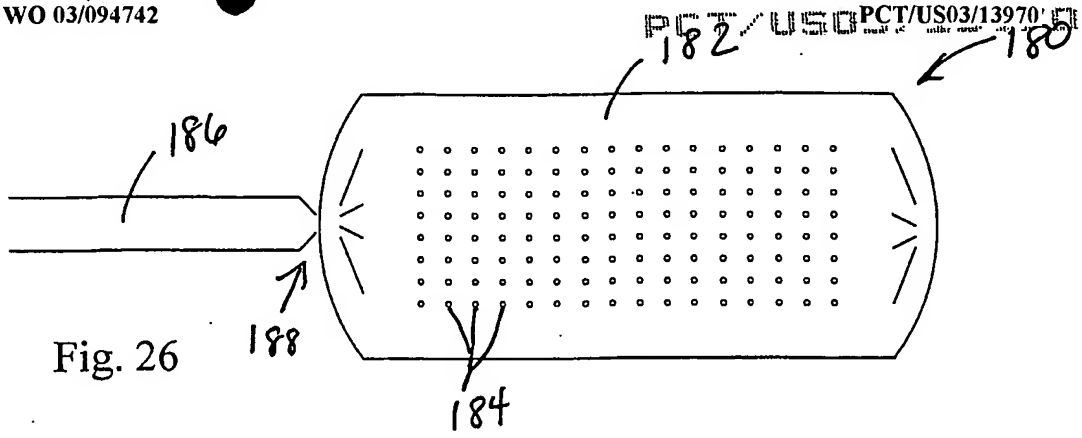

Fig. 26

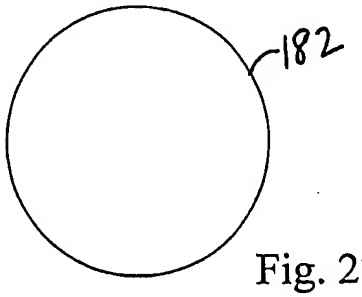

Fig. 27

Fig. 28

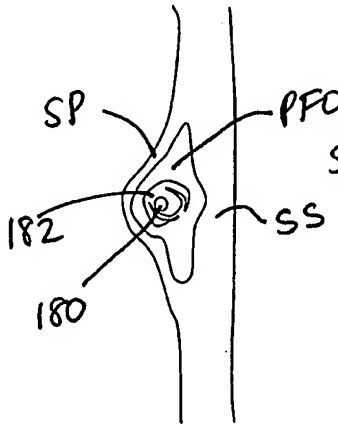

Fig. 29

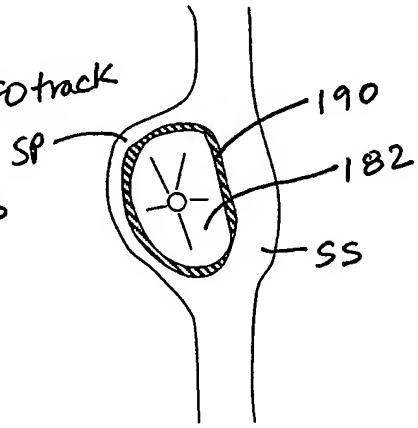

Fig. 30

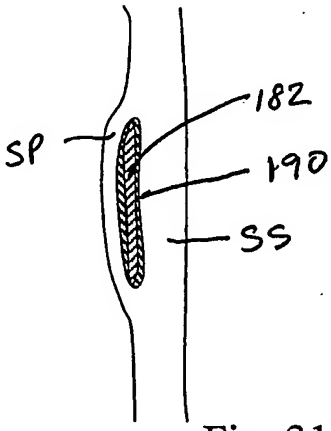

Fig. 31

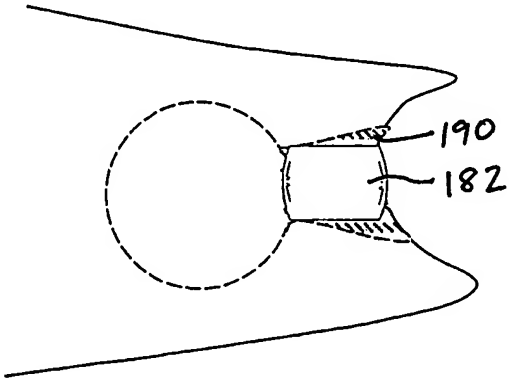

Fig. 32

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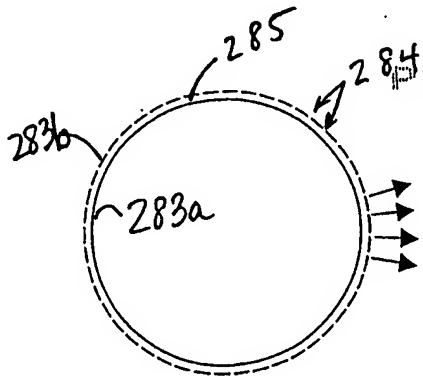

Fig. 33A

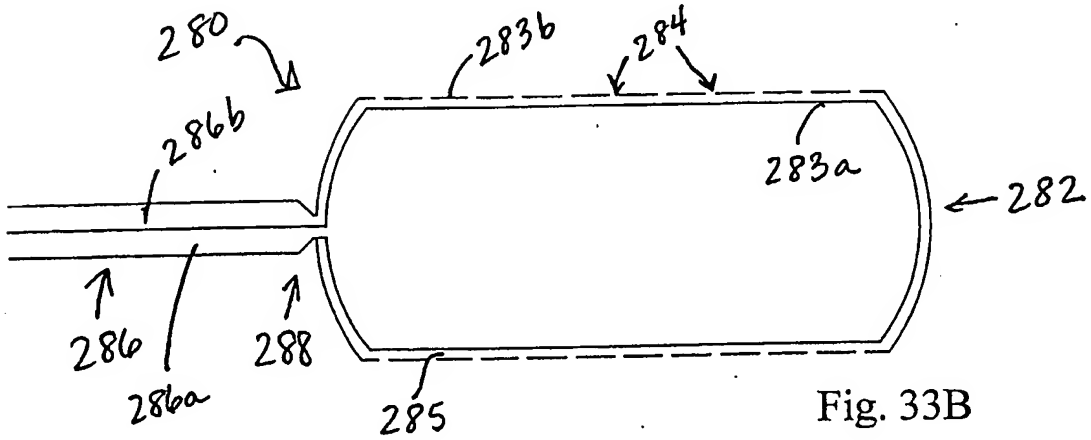

Fig. 33B

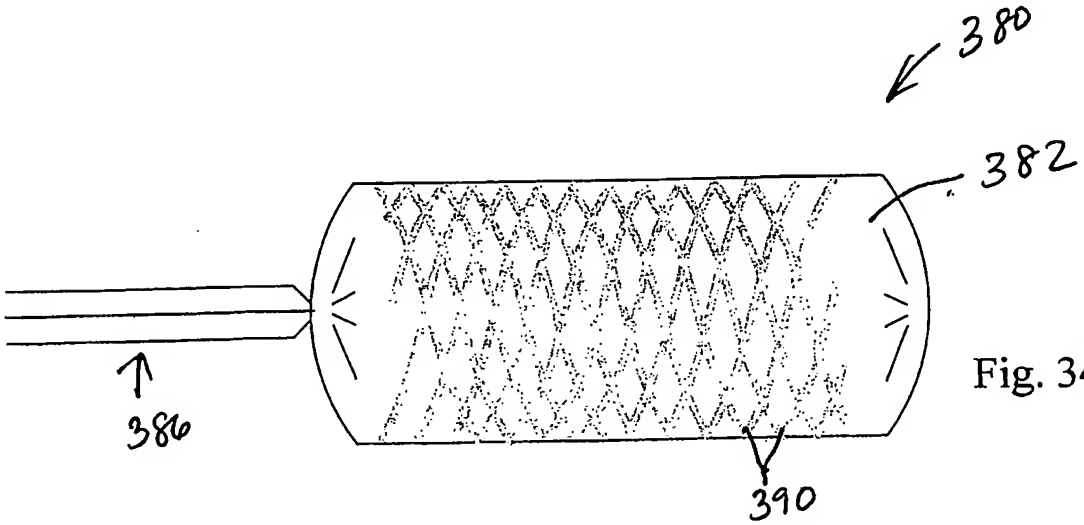

Fig. 34

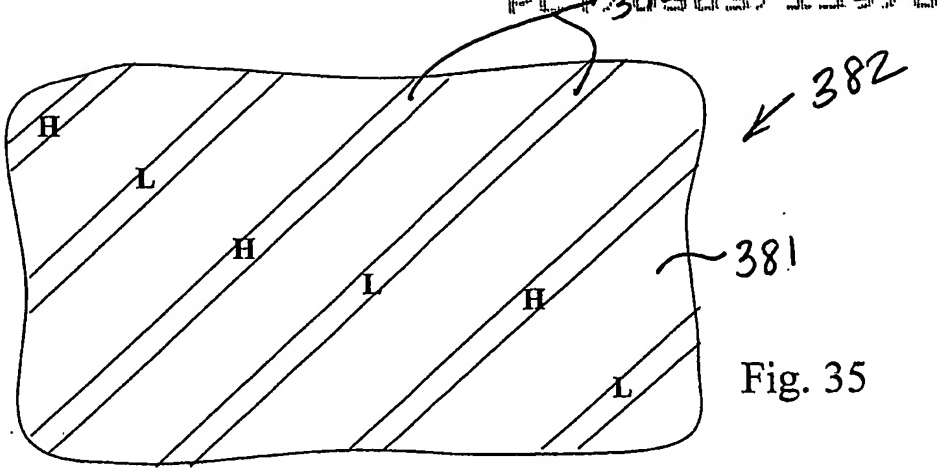

Fig. 35

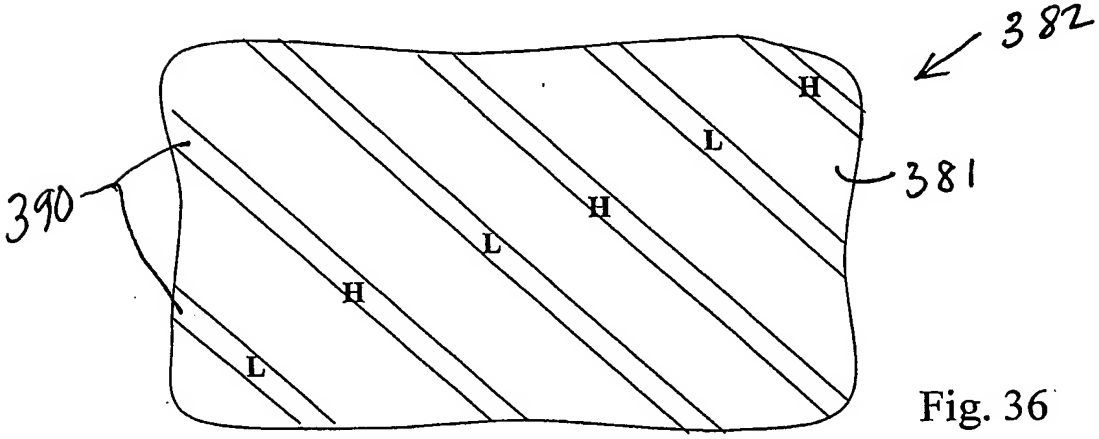

Fig. 36

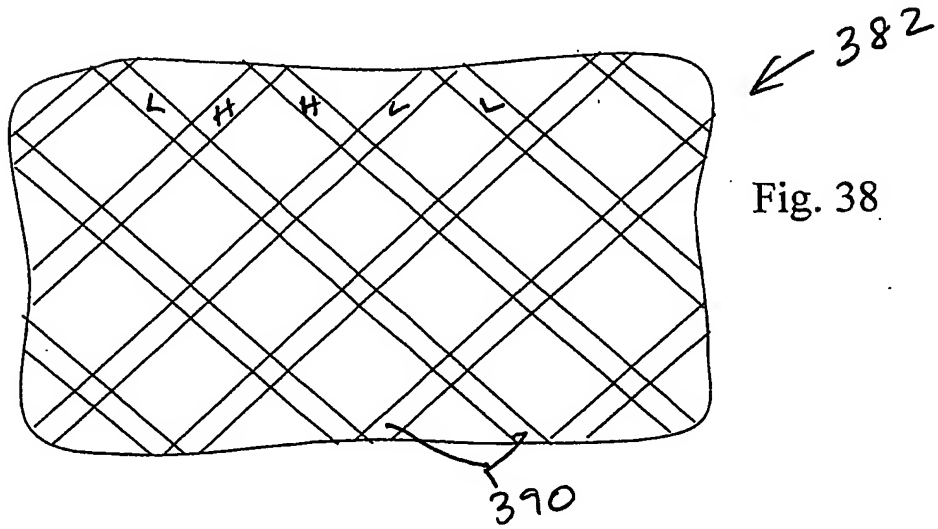

Fig. 38

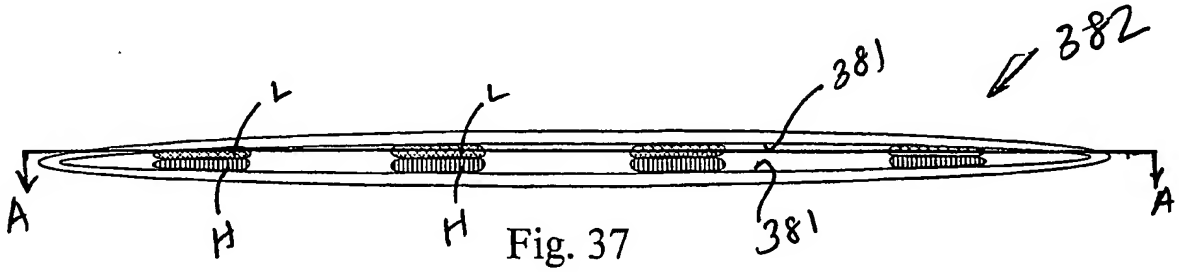

Fig. 37

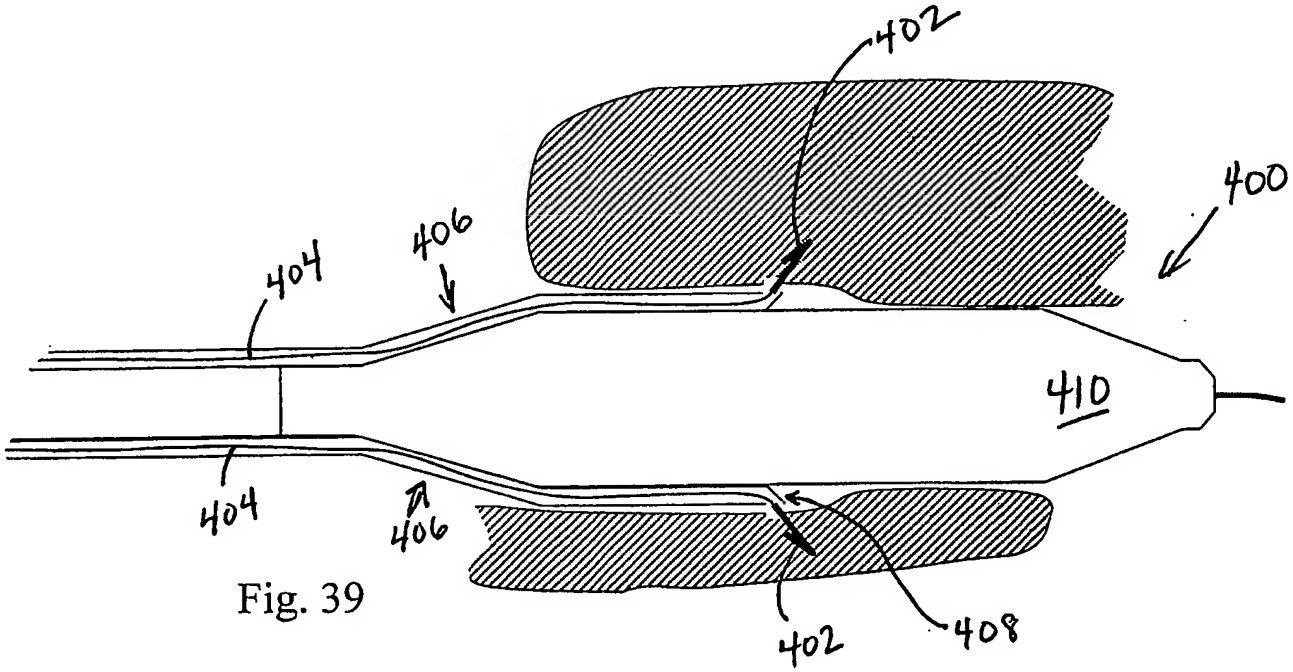

Fig. 39

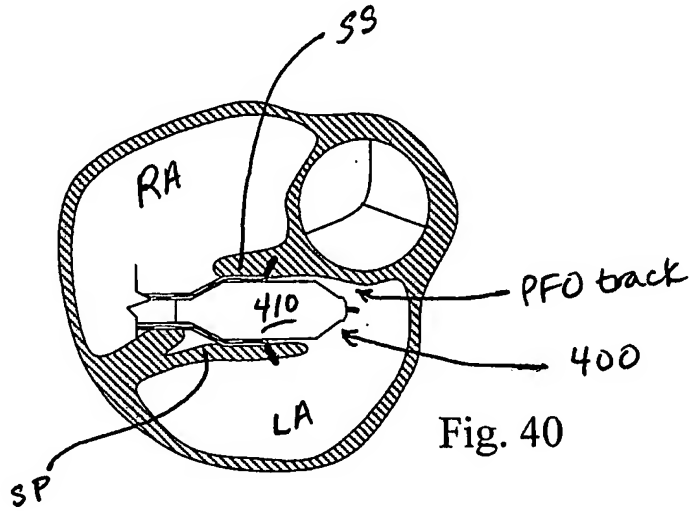

Fig. 40

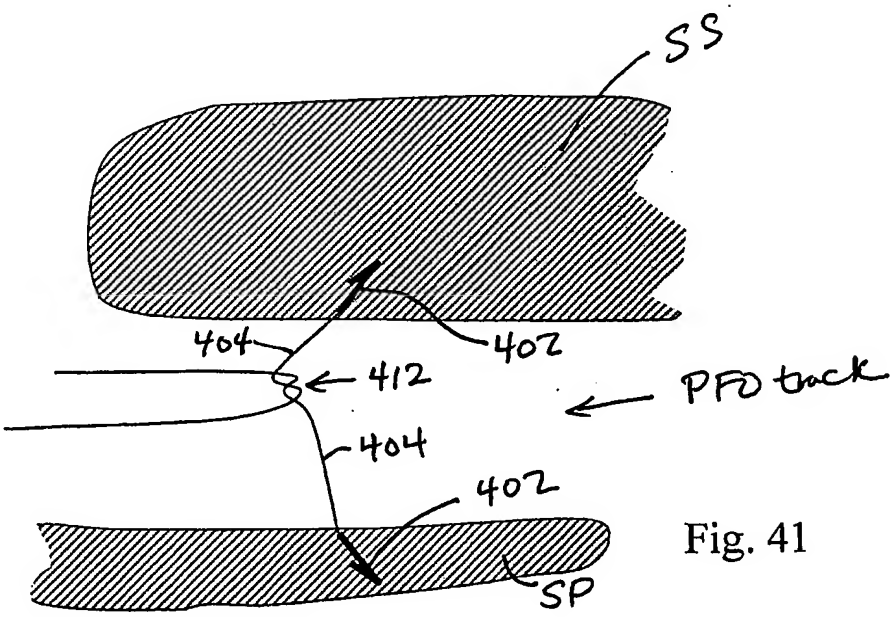

Fig. 41

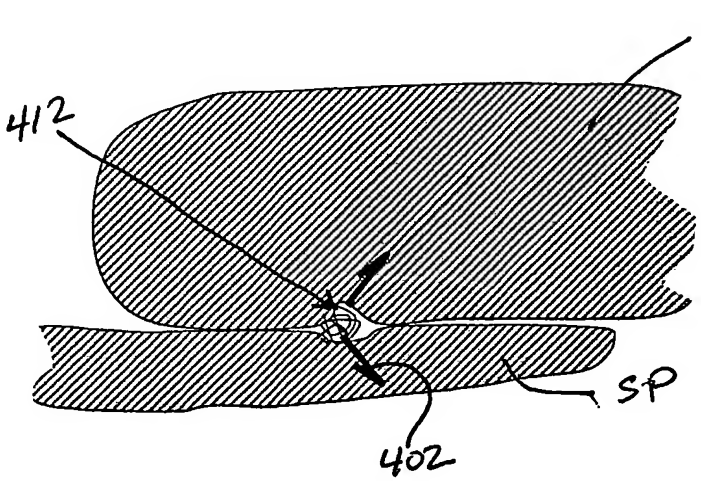

Fig. 42

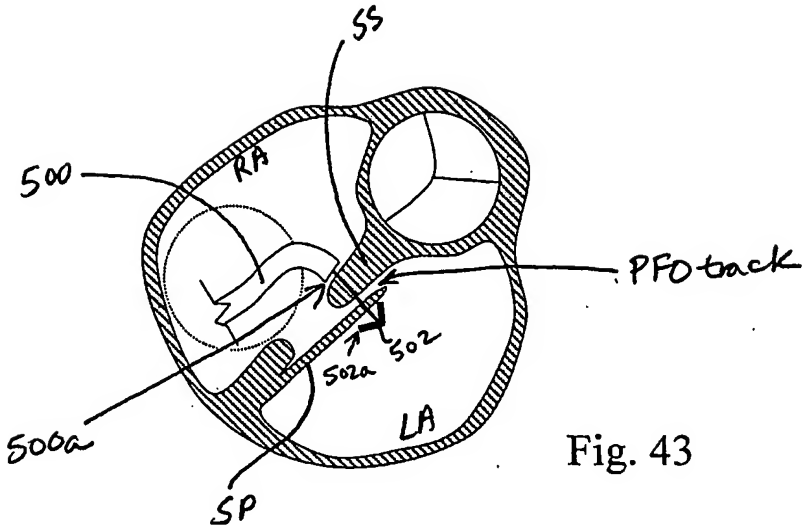

Fig. 43

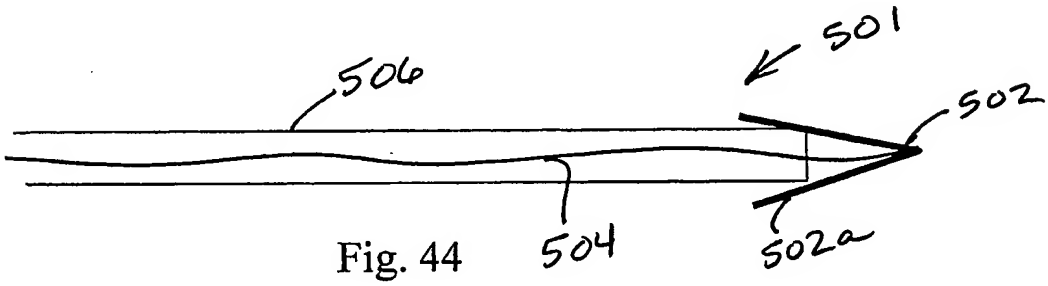

Fig. 44

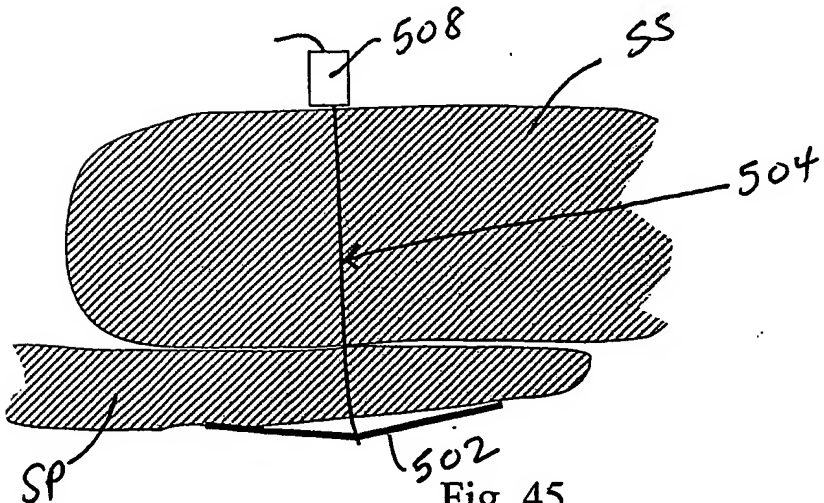

Fig. 45

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/13970

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/014800 A1 (BURG ERIK J VAN DER ET AL) 16 August 2001 (2001-08-16) the whole document	20-28, 30-37
X	US 5 868 762 A (CRAGG ANDREW H ET AL) 9 February 1999 (1999-02-09) the whole document	20-28, 30-32, 34,35,37
A	US 2002/026094 A1 (ROTH ALEX T) 28 February 2002 (2002-02-28) abstract; figures 16-19	20,30

[ ] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 October 2003	15/10/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Hansen, S

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/13970

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-19,38-98
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/13970

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